EXHIBIT 1

THE NEXT WAVE
IN PATIENT WARMING

REFUND GUARANTEE

OUR OFFER: Switch from forced-air to HotDog in your orthopedic ORs. If implant infection rates don't decline, we'll refund your money. Every penny.

"Really? How can HotDog make such an offer?"

Unlike forced-air, air-free HotDog warming doesn't generate waste heat that can contaminate the sterile field (even with laminar flow ventilation).

Hospitals that have switched to HotDog report significant reduction in deep joint SSIs. For example, a #1 rated hospital in Minnesota experienced an 81% reduction after switching to air-free warming. In the United Kingdom, a top NHS hospital dropped from a 3.1% deep joint infection rate when using forced-air to 0.81% when using HotDog warming.

"What's the catch? Where's the fine print?"

No catch...here's all you have to do:

1. HotDog must be used exclusively for 12 months...after a 2-month wash-out of existing infections.

2. The hospital must have tracked orthopedic implant infections while warming with forced-air and continue tracking while using HotDog.

3. The hospital must comply with SCIP warming standards.

That's it. If orthopedic implant infections are not reduced during the 12 month trial and the hospital wants to switch back to forced-air in its orthopedic suites, we'll take the HotDog systems back and provide a full, 100% refund.

*This refund guarantee is not intended to be a claim that HotDog warming reduces infections. It is merely an offer to refund money under the circumstances specified. The refund must be requested within 60 days of completing the trial.

**HotDog warming stands behind its products.
Unlike others, we're not blowing hot air.**

Frequently Asked Questions

1. Is Augustine claiming that HotDog warming reduces orthopedic infections?

No. Medical device "claims" must be cleared by the FDA. We do not claim that HotDog reduces infections. We do, however, fervently believe the following: If a hospital has been routinely using forced-air warming in orthopedic implant surgery and switches to air-free HotDog warming, its rate of deep infection on those implant cases will decline. Based on that belief, we are comfortable making the contractual offer.

2. Is Augustine claiming that forced-air warming causes infections?

Of course not. "Cause" has both legal and scientific meanings. To our knowledge, no court has ever determined that a forced-air warming system "caused" a surgical infection. To prove "cause" in a scientific sense would require a massive controlled, blinded study. No such study has been done...and may not even be possible.

3. What is Augustine asserting?

The facts established by published research are as follows:

a. Surgical site infections are caused by bacterial contamination of wounds.

b. Operating room ventilation systems are designed to keep contaminated air away from surgical wounds.

c. The waste heat of forced-air blowers is released near the "dirty" floor and can rise into the sterile field, defeating the protection of both conventional and laminar flow ventilation systems.

d. Bair Hugger forced-air blowers often spew millions of bacteria-sized particles per hour into the OR. The rising waste heat becomes a delivery system for these particles.

e. A single bacterium can be sufficient to cause an infection in orthopedic implant surgery.

f. HotDog warming does not blow air and does not generate significant waste heat.

That's it. Those are all the facts we know...and all the facts we assert. Based on these facts, however, we confidently offer customers our Refund Guarantee.

4. What must a customer do to get the refund?

a. Switch from forced-air warming to HotDog warming in their orthopedic surgery ORs, having standardly used FAW in the past.

b. Have tracked orthopedic implant infections for at least 24 months prior to the switch.

c. Allow for a two-month "wash-out" and then track orthopedic implant infections for the next 12 months, following SCIP warming guidelines and exclusively using HotDog warming.

d. Document that the infection rate has not fallen and switch the orthopedic surgery ORs back to forced-air warming.

e. Within 60 days of the conclusion of the trial, return the HotDog systems to Augustine and make the refund claim.

Upon confirmation that the claim is valid, we will issue a full refund.

EXHIBIT 2

e200(1)

THE ORTHOPAEDIC FORUM

Forced Air Warming Devices in Orthopaedics: A Focused Review of the Literature

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The current focus on maintaining normal body temperature in the operating room makes the use of patient warming devices routine—or even mandatory—in many hospitals. Forced air warming devices such as the Bair Hugger (3M Healthcare, St. Paul, Minnesota) maintain or increase core temperature in patients during the perioperative period, with benefits that include reduced surgical wound infections, maintenance of normal coagulation, and faster discharge from the post-anesthesia care unit (PACU)[1-5]. However, some recent literature has raised concerns regarding a possible increased risk of deep surgical site infections specifically associated with the use of the forced air warming systems in the orthopaedic operating room[5-12]. One concern is that a convective device could disrupt unidirectional downward laminar airflow, which may be especially critical in joint arthroplasty operating rooms. This concern is based on theoretical mechanisms, laboratory simulations, retrospective case series, and studies showing potentially pathogenic organisms growing in the hoses and filters of forced air warming devices[6-12]. However, multiple other studies[13-15] and a Continuing Education statement by the Association of periOperative Registered Nurses (AORN)[16] suggest that proper use of the forced air warming devices mitigates or eliminates this risk while maximizing the benefits of patient warming. The purpose of the present manuscript is to review the current literature on the use of patient warming devices in orthopaedic surgery, specifically in joint arthroplasty.

Importance of Normothermia

Hypothermia (core body temperature, <36°C) is a constant risk during general anesthesia because of factors such as impaired thermoregulation, heat loss secondary to a cold operating room, redistribution of body heat from the core to the vasodilated periphery, and infusion of cool intravenous fluids. Major adverse consequences of perioperative hypothermia can include adrenergic activation, myocardial ischemia, thermal discomfort, decreased drug metabolism, coagulopathy and increased blood loss, wound infections, prolonged recovery room stay, and increased staff and hospital costs[1,2,4,14,15]. Moreover, it is now accepted that maintaining normothermia in surgical patients substantially lowers the risk of postoperative surgical site infections[12,14,16,17]. Indeed, Kurz et al. showed that an intraoperative core body temperature decrease of only 2°C can triple the rate of soft-tissue wound infection[17]. Therefore, maintaining normothermia is a vital part of the SCIP (Surgical Care Improvement Project) measure developed by The Joint Commission and the PQRS (Physician Quality Reporting System) measure developed by the CMS (Centers for Medicare & Medicaid Services) in the U.S., and documented use of patient

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TABLE I Proper Maintenance and Use of Forced Air Warmers

Recommendations
1. The filter should be changed every 6 months or 500 hours. A counter is available on some devices (e.g., Bair Hugger 700 series) to indicate the total hours of use.
2. Calibration testing should occur every six months by biomedical engineering staff at the user's institution. The manufacturer should check or replace devices that fail calibration testing.
3. Do not warm patients with the warming unit's hose alone, as severe thermal injury may occur. Always connect the hose to a new, manufacturer-approved warming gown for each patient.
4. Do not continue warming if the red overtemperature indicator light illuminates or an audible alarm sounds, as thermal injury may result. Turn the warming unit off immediately and check the patient's skin.
5. Do not use a forced air warming device over transdermal medications; increased drug delivery and patient death or injury may result.
6. Do not allow the patient to lie on the warming unit hose or allow the hose to contact the patient's skin during patient warming.
7. Equipment is not suitable for use in the presence of a flammable anesthetic mixture (e.g., containing air, oxygen, or nitrous oxide).
8. Do not place the nonperforated side of the blanket on the patient. Thermal injury may result. Always place the perforated side (the side with small holes) toward the patient.
9. The warming device should be disconnected from the power source before cleaning. Between patients, the outside of the hose should be cleaned with a damp, soft cloth and a mild detergent or antimicrobial spray and then dried with a separate cloth.
10. If a fault occurs in the unit, unplug the temperature management unit and wait for five minutes. Reconnect the temperature management unit to a grounded power source. The unit will perform the normal power-on-reset sequence and then enter the standby mode. If the unit does not return to normal operation, contact a service technician.
11. Temperature and calibration testing should be performed every 6 months or 500 hours of use.

warming devices is a part of the requirements for receiving full reimbursement from the CMS. Any warming device may be used for the purpose of active warming intraoperatively. The goal is to maintain normothermia, or at least a body temperature of ≥36°C (≥96.8°F) recorded within the thirty minutes immediately before, or the fifteen minutes immediately after, anesthesia end time. Moreover, these normothermic goals apply to all patients, regardless of age, who are undergoing surgical procedures under general or neuraxial anesthesia lasting sixty minutes or more, although SCIP normothermia requirements are limited to colorectal procedures[18,19].

Forced air warming devices such as the Bair Hugger system rely on convective warming and definitively improve the ability of anesthesia professionals to maintain normothermia in patients undergoing abdominal and orthopaedic procedures[20-22]. Other devices (e.g., HotDog; Augustine Temperature Management, Eden Prairie, Minnesota) use conductive heating as the primary energy mechanism and may theoretically result in higher thermal efficiency compared with forced air warming[12]. The issue of rewarming patients who are already hypothermic is another challenge, as rewarming generally requires greater energy and more time compared with maintaining normothermia. Plattner et al. investigated rewarming by means of a resistive warming device (HotDog) and a forced air warming device (Bair Hugger), and they showed that core temperature increased twice as rapidly in the Bair Hugger group. The hypothermic patients randomized to forced air warming achieved a higher mean core body temperature during surgery at two, three, and four-hour time points[23].

However, Leijtens et al. showed the prevalence of hypothermia in patients undergoing major joint arthroplasty to be 26% to 28% despite the use of forced air warming, and those patients who developed hypothermia during total hip arthroplasty were 3.7 times more likely than normothermic patients to develop a periprosthetic infection[24]. Thus, maintaining normothermia during total hip arthroplasty surgery is a straightforward strategy to reduce the risk of surgical site infection—and at far less cost than the highly specialized orthopaedic laminar-air-flow operating room[25-27].

Warming Devices and Laminar Airflow

The rate of infection following joint arthroplasty involving the lower limbs is currently <1%[28]. In a multicenter study involving 8052 joint replacements, Lidwell et al. concluded that the risk of deep and superficial wound infections was substantially reduced in surgical procedures performed in operating rooms with ultraclean air ventilation compared with conventional ventilation[20]. Current ultraclean ventilation systems protect the surgical site from airborne contamination through a constant delivery of filtered air with a uniform downward velocity (0.3 to 0.5 m/s)[11,24]. This system is dependent on proper airflow volumes and temperature gradients. Unidirectional vertical airflow ventilation is more effective than horizontal ventilation, especially in combination with walls around the operating area. Body exhaust suits also reduce the number of airborne bacteria[4]. However, local sources of excess thermal energy can result in temperature gradients that interrupt the downward airflow of ultraclean air[4]. These interruptions in the velocity of downward airflow likely increase the entry of contaminants into the surgical site. Heat rising against the downward laminar airflow may also draw nonsterile contaminants up and into the surgical site.

TABLE II Alternative or Adjunctive Warming Options for Patients*

Device	Example	Benefits, Potential Risks, Contraindications
Patient warming blanket	QUINEN Warming Blanket (Shreeyash)	Covers large part of patient, making observation of skin difficult; not practical for extremity surgery
Circulating water garment	Allon ThermoWrap (MTRE)	Potential for leaking and burns as well as pressure sores; not practical for extremity surgery. Typically uses microprocessor in device
Thermal pad	Patient Warming System (Pintler)	Potential risk for cutaneous burns
Warming mattress	PerfecTemp (Medline)	Potential risk for cutaneous burns
Fluid warmer	HOTLINE (Smiths), Fluid Ranger (3M), Level 1 (Smiths)	Air emboli[40]
Reflective blanket	GRI-Alleset Healthcare or Thermoreflect patient warming products	Risk of cutaneous burns is low but may increase if combined with FAW; pressure sores may develop. Passive warming with reflective heating blankets or elastic bandages wrapped tightly around the legs were found to be ineffective in reducing the prevalence or magnitude of hypothermia[35]
Passive covering	Blanket	Increased risk of burns if used with FAW and areas of high heat develop
Conductive warming	HotDog (Augustine)	Risk of pressure sores and cutaneous burns
Forced air warming	Bair Hugger (3M)	Risk of cutaneous burns and of colonization of filter and tubing. Proper maintenance minimizes risk, and proper draping and use may decrease risk of disruption of laminar airflow

*For forced air warming (FAW) devices, the maximum contact surface temperature should not exceed 48°C, and the mean contact surface temperature should not exceed 46°C under normal conditions. For circulating liquid devices, the contact surface temperature should not exceed 43°C, and the mean contact surface temperature should not exceed 42°C under normal conditions. The fluid warming standard requires that the device does not heat the fluid above 44°C under normal conditions[41,42].

According to several recent studies, forced air warming devices may be a source of rising thermal currents that affect the normal downward airflow of laminar airflow systems[6-12]. This may raise the number of bacterial particles—as well as the temperature—over the surgical site. McGovern et al. reported an infection rate of 3.1% with use of forced air warming compared with 0.8% with a conductive warming device[12]. The authors suggested that discontinuing the forced air warming would decrease the infection rate by 74%[10,11]. Legg et al. showed that forced air warming devices increased the mean temperature and the number of particles over the surgical site, thereby increasing the number of pathogens over the surgical site[10,11]. However, several of those studies were funded by the manufacturers of competing devices[6-10,12]. Most studies on the use of forced air warming devices and other warming technologies in combination with laminar airflow are clearly underpowered and poorly controlled, and conclusions regarding the independent effect of the warming devices on surgical site contamination and infection are uncertain[15,29].

Other studies (again, usually industry-funded) have indicated that forced air warming does not increase the risk of particulate dispersion near surgical sites[13,22,30-34]. These studies have shown that perioperative temperature management with forced air warming actually decreases the risk of surgical site infection. Sessler et al.[32] conducted a simulation study similar to that of McGovern et al.[12] and showed that forced air warming did not reduce air quality in an operating room with laminar flow ventilation. No difference in infection rate was evident in a series of patients undergoing vascular, breast, and hernia surgery who were warmed with either a conductive heating or forced air warming (Bair Hugger) device. However, patients who did not have any warming device did have a higher rate of infection[27]. The authors of several systematic reviews have recommended the use of forced air warming because of its improved ability to maintain normothermia and suggested that it has little role in disrupting laminar airflow[5,31,35]. Thus, the literature appears to indicate that forced air warming can impact laminar flow under certain very specific conditions, but any actual clinical impact on surgical site infections must be considered unproven at this time. On the basis of the current evidence, it is likely that both forced air warming and conduction-based warming decrease the risk of hypothermia in orthopaedic patients undergoing arthroplasty, and maintenance of normothermia is critical to a strategy for minimizing surgical site infections. Neither type of device can completely eliminate the risk of hypothermia, and both share risks of adverse side effects such as burns and pressure sores[36]. Indeed, all medical devices require training, education, and maintenance for proper use.

TABLE III Articles Evaluating Forced Air Warming Devices*

	Albrecht 2009[7]	Albrecht 2011[6]	Belani 2013[8]	McGovern 2011[12]	Legg 2012[10]	Dasari 2012[9]	Legg 2013[11]	Reed 2013[38]
Study design	Lab. expt.	Lab. expt.	Lab. expt.	Retrospective case series	Lab. expt.	Lab. expt.	Lab. expt.	Lab. expt.
Simulated or actual patients	Simulated	Simulated	Simulated	Patients undergoing THA and TKA	Simulated	Simulated	Simulated	Simulated
No. of patients or subjects	Hospitals, n = 5. Particle counts, n = 25. Swabbing, n = 17. Rinsing, n = 9	11	2 per group	1437 with 371 treated with conductive warmer and 1066 with FAW	5	5 locations at 5 heights	5	1 hospital with 23 FAW units
End points	Particle counts	Intake filter retention efficiency/ performance, airborne particles, FAW colonization	Bubble count over the simulated surgical site	Infection	Particle counts and temp. over surgical site	Temp. at simulated surgical site	Airflow visualization, drape temp., and particle entrainment	Intake filter efficiency/ performance and air path microbial colonization
Statistical significance	No	No	Yes	Yes	Yes	Yes	Yes	No
Summary of findings	FAW equipment design is questionable with respect to its ability to prevent airborne contamination	58% of FAW units were found to generate airborne contamination. No direct link between infection and FAW. New filters may improve efficiency	FAW disrupted laminar airflow; disruption was dependent on the exact setup of the room	High risk of developing deep infections with FAW use (odds ratio = 3.8, p = 0.024)	Temp. over surgical site and the no. of particles were greater with FAW. Unable to definitively conclude that these are causes of infection	Greater temp. over the surgical site with FAW vs. conductive warming and resistive blanket	Disruption of laminar airflow and increased no. of particles over the surgical site with FAW. Drape temp. also increased. Authors suggested certain OR setups may impact laminar flow	Filter efficiency was 64% in lab. experiments but filters performed within specifications in the OR. 70% of FAW units had higher particle counts at the hose end compared with the intake
Study limitations	Testing was done without the blanket, which is required for proper airflow. Did not demonstrate that detected particles were bacteria. Author conflict of interest	Testing was done without the blanket, which is required for proper airflow. No demonstration of proper maintenance of filters and FAW units. Author conflict of interest	Did not control for room setup. Author conflict of interest	Coauthor was employee of conductive warming company. Did not account for age or medical comorbidities. Assumed causation. Did not account for other infection control measures implemented during study period	Did not simulate OR traffic and personnel	Assumed higher temp. at surgical site increases risk of infection. Did not simulate normal OR traffic. Author conflict of interest	No direct relationship shown between laminar airflow being affected and increased bacteria over surgical site	Relied on particle counts rather than sampling of microorganisms from hose-end airflow. High percentage of control swab contamination (50%). Testing was done without blanket

*THA = total hip arthroplasty, TKA = total knee arthroplasty, FAW = forced air warming, OR = operating room, ICU = intensive care unit, and CFU = colony-forming unit.

Proper Use of Equipment and Drapes

The primary heating unit in forced air warming devices requires cleaning and routine maintenance (Table I). Delayed or deficient maintenance may result in adverse events. Gjolaj et al.[26] described the results of bacterial testing of Bair Hugger units. After six months or more than 500 hours of usage (the time at which the manufacturer recommends installation of new filters), the distal end of the outflow hose was positive for

TABLE III (*continued*)

Baker 2002[39]	Bernards 2004[37]	Huang 2003[13]	Sharp 2002[33]	Tumia 2002[22]	Sessler 2011[32]	Zink 1993[34]	Moretti 2009[31]	Avidan 1997[30]
Lab. expt.	Lab. expt.	Retrospective case series	Lab. expt.	Clinical study	Lab. expt.	Clinical study	Retrospective case series	Lab. expt.
Neither	Neither	Patients undergoing aortic surgery with prosthetic graft	Simulated	Actual patients and lab. simulation	Simulated	Actual patients but simulated surgery	Actual	Neither
1 FAW system	1 FAW system	16 patients	12 different conditions ranging from empty ORs to various volunteers with FAW	6	2	8	30 patients, 20 who received FAW and 10 who did not	10 FAW systems from ORs
Cultures of FAW hose and filter	Cultures of FAW hose and filter	Culture sites on patient and in FAW system	Assessment of laminar flow using smoke visual tracer	Increase in number of CFUs	Assessment of laminar flow using smoke visual tracer	Culture sites of abdomen	Infections and culture sites on patient and in FAW system	Cultures of filter and hose
No	No	No	No	No	No	Yes	No	No
Heavy growth of bacteria from all sites	Same strain of Acinetobacter as that responsible for an outbreak. After device was cleaned, the bacteria were not found	Decrease in bacterial counts at all 6 sites, including the axilla and the FAW system	No significant effect of FAW use on laminar airflow	Nonsignificant increase in CFUs when FAW was on compared with when it was off ($p = 0.48$)	No impairment of laminar flow and no unwanted airflow disturbances using FAW	More coagulase-negative colonies when FAW system was off ($p < 0.05$), but overall no difference in total no. of colonies between when it was on and off	No postoperative infections	40% of FAW system hoses had potentially pathogenic organisms. 100% showed no growth from the air when the FAW system blanket was worn
Only a single device was tested	Only a single device was tested. The study was a part of an investigation into an Acinetobacter outbreak in the ICU	Small number of patients. No mention of air handling method in the OR	Did not simulate normal OR traffic	Unknown patient characteristics. Unknown manufacturer of FAW system	Did not simulate normal OR traffic	Skin was not prepped. No surgical team was present and no surgery was performed on patients. Only skin flora was assessed	Unknown follow-up period. Unknown location of FAW cover. Small no. of patients	Positive cultures from tubing may not be associated with infection in the patient

bacterial growth in twelve of twenty-nine units, and the filter was positive in three units. Routine care that included changing of the filter and cleaning of the unit was then performed, and the testing was repeated after three months. The repeat cultures of the units with a previous positive culture showed no growth in the tubing or filter. This suggests that proper maintenance of the Bair Hugger is essential to reduce the risk of infection. Other studies have also revealed measurable growth of bacteria in ventilation filters, and the authors attributed the cause of infection outbreaks to colonized filters[6,7]. Frequent maintenance of the forced air warming units and cleaning of the outside and tubing of the warming unit are required to reduce

colonization and the associated risk to the patient. Some authors even propose the addition of an HEPA (high-efficiency particulate air) antimicrobial filter to forced air warming systems, but relevant studies are lacking[30,37-39].

Legg and Hamer simulated the impact of surgical drapes and equipment on forced air warming devices and laminar flow in an operating room environment[11]. For instance, the authors noted that, depending on the arrangement of medical equipment in the operating room, forced air warming devices may be more likely than conductive warmers to disrupt laminar airflow around the surgical field. They also noted that even the use of a vertical drape between the surgical field and the anesthesia team at the head of the table affects the laminar flow. Surgical drapes placed vertically as part of the sterile surgical field may themselves be warmed by forced air warming devices, leading to accessory convection currents traveling upward and disrupting downward laminar flow. Indeed, the authors suggest that if the artificial enclosure created by the vertical drape is eliminated, the production of additional heat is less likely to be important because warm air can leave more easily. They recommend using a well-insulated surface that is not in contact with the patient to distribute the additional heat that may otherwise be transferred to the drape. The authors further recommend putting the vertical drape up before the Bair Hugger is turned on, ensuring that the Bair Hugger is properly connected to the gown with no leaks, and following all manufacturer instructions regarding the placement of the gown. Clearly, proper use of forced air warming devices and associated warming gowns is required to maximize heat transfer to the patient while minimizing heat transfer to the drapes and surrounding laminar airflow.

The risks of burns and pressure sores, even involving the nonoperatively treated extremity, increase when warming devices are not used properly. Burns can result from improper placement of the warming device or from placement of the tubing on the patient. Mayo stands, trays, and surgical equipment placed on or near a patient can limit expansion of the warming blanket or gown. This can force air into a small area and increase the risk of burns. These burns are often first or second-degree and may heal with scarring. Appropriate consultation with plastic surgeons or wound nurses may allow for prompt treatment and skin coverage as needed. There are also several alternatives or adjunctive warming devices that may be used to increase patient temperature. Some of these devices and their risks and benefits are described in Table II. Several studies have indicated that the use of these devices in addition to forced air warming increases the ability to maintain normothermia[35,40-42].

Clinical Importance

It is important to consider both the risks and benefits of warming devices when deciding how to utilize them for patients undergoing joint arthroplasty. There are medical, safety, and economic implications to the choice[43,44]. Further study is warranted to prove or disprove a causal relationship between use of forced air warming and periprosthetic joint infections (Table III). In the meantime, appropriate strategies include proper maintenance of equipment and filters to reduce bacterial colonization, appropriate placement of forced air warming blankets in accordance with manufacturer recommendations, and recognition of the potential effects of these devices on laminar airflow. Future studies will need to limit bias, include large study populations, have a consistent definition of hypothermia, carefully control associated and relevant variables (e.g., operating room traffic and antibiotic protocols), and ensure equivalent efficacy of warming in all study groups. Such studies will aid clinicians in choosing appropriate future strategies for warming. ■

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EXHIBIT 3

CONTINUING EDUCATION

Forced-Air Warming Devices and the Risk of Surgical Site Infections

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Purpose/Goal

To provide knowledge specific to the use of forced-air warming systems and surgical site infections.

Objectives

1. Describe inadvertent perioperative hypothermia.
2. Discuss the use of forced-air warming to maintain normothermia perioperatively.
3. Describe the methodologies used in the studies appraised in this article.
4. Describe the authors' conclusions about the use of forced-air warming systems.

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Conflict of Interest Disclosures

Melissa D. Kellam, DNAP, CRNA; Loraine S. Dieckmann, PhD; and Paul N. Austin, PhD, CRNA, have no declared affiliations that could be perceived as posing potential conflicts of interest in the publication of this article.

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Forced-Air Warming Devices and the Risk of Surgical Site Infections

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ABSTRACT

The potential that forced-air warming systems may increase the risk of surgical site infections (SSIs) by acting as a vector or causing unwanted airflow disturbances is a concern to health care providers. To investigate this potential, we examined the literature to determine whether forced-air warming devices increase the risk of SSIs in patients undergoing general, vascular, or orthopedic surgical procedures. We examined 192 evidence sources, 15 of which met our inclusion criteria. Most sources we found indirectly addressed the issue of forced-air warming and only three studies followed patients who were warmed intraoperatively with forced-air warming devices to determine whether there was an increased incidence of SSIs. All of the sources we examined contained methodological concerns, and the evidence did not conclusively suggest that the use of forced-air warming systems increases the risk of SSIs. Given the efficacy of these devices in preventing inadvertent perioperative hypothermia, practitioners should continue to use and clean forced-air warming systems according to the manufacturer's instructions until well-conducted, large-scale trials can further examine the issue. *AORN J* 98 (October 2013) 354-366. © AORN, Inc, 2013. http://dx.doi.org/10.1016/j.aorn.2013.08.001

Key words: *intraoperative hypothermia, normothermia, forced-air warming, surgical site infection.*

Patients often report feeling cold before the induction of general anesthesia or when sedated for surgical procedures. Besides being uncomfortable, inadvertent perioperative hypothermia can be difficult to treat and have undesirable consequences for the patient, including platelet dysfunction and other coagulation defects, delayed postanesthetic recovery, prolonged hospitalization, and surgical site infections (SSIs).[1] Inadvertent perioperative hypothermia, defined as a core body temperature of $\leq$ 36.0° C (96.8° F), is the most common thermal disturbance seen in surgical patients.[1] Reasons for heat loss during operative and invasive procedures include the patient's exposure to the surgical environment and the effects of anesthetic agents and medications that interfere with the body's normal ability to regulate temperature.[1] A major physiological reason for anesthesia-related hypothermia is a redistribution of heat from the core to the periphery of the body because of vasodilation effects caused by volatile anesthetic agents.[1] There is also a similar effect seen with major regional anesthesia (eg, spinal, epidural).[1]

Health care providers often use forced-air warming systems to provide surface warming in the

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OR because these devices are helpful in maintaining normothermia and preventing perioperative hypothermia.[2] However, providers also are concerned that these devices may increase the risk of SSIs by acting as a vector or causing unwanted airflow disturbances over the surgical site. Because of the perceived infection risk, some surgeons request these devices not be turned on until the patient is prepped and draped or that they not be used at all.[2] To investigate this risk, we used the following PICO (ie, population, intervention[s], comparison, outcome) question[3] to guide our search for evidence: Do forced-air warming devices increase the risk of SSIs in patients undergoing general, vascular, or orthopedic surgical procedures?

SEARCH STRATEGY

To answer our question, we examined the literature to determine whether forced-air warming devices increase the risk of SSIs in patients undergoing general, vascular, or orthopedic surgical procedures. We included evidence from high-level sources, including systematic reviews with or without meta-analysis, clinical practice guidelines, and human clinical studies. We also included lower-level studies, which included laboratory and simulation studies, because we suspected that there would be a lack of higher-level evidence to answer our question. We revised our search in an ongoing fashion to refine the search results.

We gathered our evidence by searching PubMed®, Academic Search™ Complete, and the Cochrane Collaboration databases for the period from 1990 to 2012. We used the following search terms alone and in combination: *convection warmer, convection warming, forced air warmer, forced air warming, infection, contamination*, and *complications*.

Our inclusion criteria included full-text articles in English that addressed the PICO question and were published in peer-reviewed journals or on specialty or government web sites. The population of interest included patients of all ages undergoing general, vascular, or orthopedic procedures. We appraised the evidence based on whether it helped answer the PICO question and for methodological quality using the method described by Stetler et al.[4] Two authors (MDK and PNA) evaluated each evidence source, and consensus was reached when there was disagreement. We further scrutinized the reference lists of appraised evidence, including using the "related citations" function in PubMed, to locate further applicable evidence that met our inclusion criteria.

CRITICAL APPRAISAL OF THE LITERATURE

Our search yielded a total of 192 possible sources. Fifteen sources[5-19] remained after we eliminated those that were duplicates or did not meet our inclusion criteria. We did not find any systematic reviews. The investigations we reviewed used four general methods to determine the likelihood of the forced-air warmer causing an SSI, with some studies using more than one method. The direct method was to follow patients who were warmed intraoperatively with a forced-air warmer to determine whether it led to an increased incidence of SSI,[12,14,15] and the three indirect methods were to

- examine the intake, inside, and output hoses of forced-air warming units or the air emitted directly from the forced-air warming unit for bacteria or particles that might harbor bacteria[5-8,10,12];
- evaluate bacterial counts near or on patients, volunteers, or manikins in an OR[12,15,17-19]; and
- examine unwanted airflow disturbances in the OR caused by the forced-air warming device.[9,11,13,14,16,17]

It is important to note that only one of these methods, which was used in three investigations, directly examined the likelihood of an increased incidence of SSIs caused by the intraoperative use of forced-air warmers.[12,14,15] The remaining three methods used by the other investigators indirectly examined the likelihood of forced-air warmers to cause SSIs.

Methodological Concerns

There were numerous methodological concerns with all of the investigations that we reviewed.[5-19] For example, none of the researchers described how they determined the sample size of forced-air warmers or the number of study participants. In addition, none indicated whether the forced-air warmers had been maintained per the manufacturer's instructions. They also did not perform any blinding or random allocation of participants to study groups. An important concern is that five[5,6,9,11,14] of the investigations included an author who was supported or had been supported by a company that manufactures a conductive fiber blanket that was in direct competition with makers of forced-air warming systems. Another study was supported by a forced-air warmer manufacturer.[16] We felt these represented sources of potential bias.

Direct Methods

Three investigations[12,14,15] followed patients who were warmed intraoperatively for SSIs (Table 1). All of these studies were observational studies and were part of other investigations examining bacterial counts near or on patients or manikins. One of the

TABLE 1. Summary of Evidence: Observing Subjects Who Were Warmed Intraoperatively Using a Forced-Air Warmer for Infection

Evidence source[a]	Subjects, procedure, and intervention	Findings and comments[b]
Huang JK, Shah EF, Vinodkumar N, Hegarty MA, Greatorex RA. The Bair Hugger® patient warming system in prolonged vascular surgery: an infection risk? *Crit Care*. 2003;7(3):R13-R16.	■ 16 subjects ■ Aortic surgery with graft ■ Forced-air warming system[c] with upper body cover (mean 234 minutes)	■ No postoperative surgical site infections at six months
McGovern PD, Albrecht M, Belani KG, et al. Forced-air warming and ultra-clean ventilation do not mix: an investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics. *J Bone Joint Surg Br*. 2011;93(11):1537-1544.	■ 1,437 subjects ■ Hip or knee replacement ■ Forced-air warming system[c] (n = 1,066 subjects) or conductive fiber blanket[d] (n = 371 subjects)	■ High risk of developing deep infections for subjects warmed with forced-air warming system (odds ratio, 3.8; $P = .024$) ■ No effect of factors such as age or diabetes ■ No records on blood transfusions, incontinency, or overall physical status ■ No control of potentially confounding factors ■ Unknown what effect history played on the results because data were collected during a two-year study period
Moretti B, Larocca AM, Napoli C, et al. Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection? *J Hosp Infect*. 2009;73(1):58-63.	■ 30 subjects ■ Hip replacement ■ Forced-air warming system[c] (n = 20 subjects) or no forced-air warmer (n = 10 subjects)	■ No postoperative surgical site infections ■ Unknown follow-up period ■ Unknown location of forced-air warmer cover

[a] *All observational studies, Level IV C evidence*
[b] *No mention of randomization, patient selection, sample size calculation, or blinding*
[c] *Bair Hugger®*
[d] *Hot Dog Total Access Warming™*
Bair Hugger is a registered trademark of Arizant Healthcare, Eden Prairie, MN. Hot Dog Total Access Warming is a trademark of Augustine Temperature Management, Eden Prairie, MN.

investigations also looked at the effect of forced-air warmers on unwanted airflow in the OR.[14]

Huang et al[12] included 16 vascular surgery patients but had no control group.[12] Moretti et al[15] examined a total of 30 female patients who underwent hip replacement surgery: 20 who received forced-air warming and 10 who did not. Neither of these studies included a comparison of groups for equivalence. The third direct investigation included 1,437 patients undergoing hip or knee replacement.[14] A forced-air warmer was used with 1,066 patients from July 2008 to March 2010 and a conductive fiber blanket was used with 371 patients from March to June 2010. The authors acknowledged that the presence of potential confounders, such as antibiotic use and thromboprophylaxis, had changed between 2008 and 2010 and could have affected the subjects' risk of SSI.[14] The groups were similar in some respects, including the type of surgery and the presence of diabetes; however, the groups were not compared in terms of other potentially confounding variables, including obesity, incontinence, and fitness for surgery.

McGovern et al[14] described the OR used as being a laminar flow room with ultra-clean air; however, the other studies[12,15] did not describe the type of OR air handling. Because the rooms were functioning ORs, we assumed the air handling met regulative standards. In addition, in one study, the method of following the subjects for SSI was not detailed.[14]

Indirect Methods

The first method that researchers used to indirectly examine whether forced-air warmers are likely to cause SSIs was to look at the incidence of forced-air warmers harboring organisms (Table 2). Six evidence sources[5-8,10,12] examined various locations in or on the forced-air warming device or the air emitted directly from the unit's output hose for bacteria or particles that might harbor bacteria. Methods used to determine this ranged from researchers simply swabbing the interior and exterior of one forced-air warmer, including the inside of the output hose, and culturing the samples in growth media[8] to examining the filtration efficiencies of 25 forced-air warmers from five hospitals.[6]

Albrecht et al[5] compared the filtration efficiency of five new forced-air warmer intake filters with five used intake filters of an older design. Baker et al[8] and Bernards et al[10] examined only a single forced-air warmer. Investigators thoroughly described the methods used to gather air and surface samples. The study by Bernards et al[10] was not a description of an SSI outbreak but of an outbreak of *Acinetobacter baumannii* in an intensive care unit. The strain researchers cultured from affected patients was the same strain cultured from the dust filters of the forced-air warmer used in the affected patient rooms. The authors also noted that staff members were not changing the unit filters per the manufacturer's instructions. The presence of bacteria in or on these devices is a surrogate for SSI incidence; it does not establish a causal relationship to SSIs because the incidence of SSIs in subjects warmed by a forced-air warmer was not examined.

The second indirect method used[12,15,17-19] to determine whether forced-air warmers are likely to cause SSIs was to examine bacterial counts near or on patients[12,15,18] or volunteers[17,19] or near where the site of surgery would most likely be in an empty OR[17] (Table 3). Researchers obtained samples from the surgical site,[12,15,19] near the surgical site,[17] and close to the middle of the OR.[18] The investigators clearly described the methods used to gather samples and culture bacteria. We assumed, but this was not identified in the studies, that all ORs met air handling standards. Only two studies[17,18] described the OR as using "ultra-clean" air handling. Conditions were not standardized. For example, some investigators did not include a surgical team or traffic in the OR,[17,19] and the setting for other studies[12,15] was a working OR during actual procedures.

The final indirect method used to help determine the likelihood of forced-air warmers causing SSIs was to examine unwanted airflow disturbances caused by the air emitted from the forced-air warmer cover placed on the patient (Table 4).[9,11,13,14,16,17]

TABLE 2. Summary of Evidence: Incidence of Forced-Air Warmers Harboring Organisms

Evidence source[a]	Number of devices examined	Culture sites	Findings	Comments[b]
Albrecht M, Gauthier R, Leaper D. Forced-air warming: a source of airborne contamination in the operating room? *Orthop Rev (Pavia)*. 2009;1(2):e28.	■ 25 forced-air warming systems[c,d] from 5 hospitals	■ Air from intake and output hoses, interior of intake and output hoses	■ 8 of 25 forced-air warming systems had lower filtration efficiencies ■ 17 forced-air warming systems had bacteria cultured from inside 71% of intake and 88% of output hoses ■ 9 forced-air warming systems had 89% positive cultures from the liquid from rinsing the inside of the output hose	■ Implied forced-air warming systems emitting internally generated contamination within the size range of free-floating bacteria (< 4 µm)
Albrecht M, Gauthier RL, Belani K, Litchy M, Leaper D. Forced-air warming blowers: an evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control*. 2011;39(4):321-328.	■ 52 forced-air warming systems[c] ■ 5 new intake filters[c] ■ 5 used intake filters[c]	■ Internal air path surfaces, hose outlet particle counts	■ Newer filters had 93.8% retention efficiency ■ Used filters had 61.3% retention efficiency ■ 92.3% of forced-air warming system blowers had bacteria cultured from internal air path surfaces	■ Increased efficiency of new filters may be because of design change ■ Approximately 58% of forced-air warming blowers were internally generating and emitting airborne contaminants
Avidan MS, Jones N, Ing R, Khoosal M, Lundgren C, Morrell DF. Convection warmers—not just hot air. *Anaesthesia*. 1997;52(11):1073-1076.	■ 10 forced-air warming systems[e] from various ORs	■ Multiple locations	■ 4 out of 10 forced-air warming systems' output hoses harbored potentially pathogenic organisms ■ 10 out of 10 showed no growth from air from the forced-air warming system blanket when perforated ■ The upstream side of the filter showed evidence of colonization	■ Fitting the outlet hose with a filter may prevent emission of bacteria from forced-air warming systems

TABLE 2. *(continued)* Summary of Evidence: Incidence of Forced-Air Warmers Harboring Organisms

Evidence source[a]	Number of devices examined	Culture sites	Findings	Comments[b]
			■ Organisms included *Staphylococcus epidermidis* ■ There was no organism growth when the output hose was fitted with a filter[f]	
Baker N, King D, Smith EG. Infection control hazards of intra-operative forced air warming. *J Hosp Infect*. 2002;51(2):153-154.	■ 1 device[g]	■ The interior and exterior of the forced-air warming systems and the inside of the output hose	■ "Heavy growth" of bacteria was obtained from all sites	
Bernards AT, Harinck HI, Dijkshoorn L, van der Reijden TJ, van den Broek PJ. Persistent *Acinetobacter baumannii*? Look inside your medical equipment. *Infect Cont Hosp Epidemiol.* 2004;25(11): 1002-1004.	■ 1 device[c]	■ The exterior and internal forced-air warming system filters	■ The same strain of *Acinetobacter baumannii* caused an outbreak ■ The organism was not cultured after the dust inside the forced-air warming systems was removed	■ The study was part of an investigation of an *Acinetobacter baumannii* outbreak in a medical intensive care unit
Huang JK, Shah EF, Vinodkumar N, Hegarty MA, Greatorex RA. The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk? *Crit Care.* 2003; 7(3):R13-R16.	■ Unknown number of ORs and unknown number of forced-air warming systems ■ 16 patients undergoing aortic surgery with prosthetic graft (mean 234 minutes, range 180-270 minutes)	■ Forced-air warming systems[c] with upper body cover ■ 6 sites including around the OR, near the axilla, near the wound edge, forced-air warming system[c] filter, and output hose at various times during the procedure	■ Decrease in bacterial counts at all 6 sites	■ No mention of the air handling method used in the OR, but presumably it met standards

[a] All studies were Level IV C evidence
[b] No mention of sample size calculation or whether forced-air warming systems were maintained according to the manufacturer's instructions
[c] Bair Hugger®
[d] Unknown forced-air warming system manufacturer, forced-air warming systems, or forced-air warmer
[e] 9 Bair Hugger systems, 1 Warm Touch™
[f] DAR Hygrobac filter™ for breathing systems
[g] WarmAir®

Bair Hugger is a registered trademark of Arizant Healthcare, Eden Prairie, MN. Warm Touch and DAR Hygrobac filter are trademarks of Covidien, Mansfield, MA. WarmAir is a registered trademark of Cincinnati Sub-Zero, Cincinnati, OH.

TABLE 3. Summary of Evidence: Bacterial Counts Near or on Patients, Volunteers, or Manikins During Forced-Air Warmer Use

Evidence source[a]	Setting and subjects	Interventions	Sites sampled	Findings	Comments[b]
Huang JK, Shah EF, Vinodkumar N, Hegarty MA, Greatorex RA. The Bair Hugger® patient warming system in prolonged vascular surgery: an infection risk? *Crit Care.* 2003;7(3): R13-R16.	■ Unknown number of ORs	■ 16 patients undergoing aortic surgery with prosthetic graft (ie, mean 234 minutes, range 180-270 minutes) ■ Forced-air warming system[c] with upper body cover	■ 6 sites including around the OR, near the axilla, and near the wound edge ■ Filters and output hoses were sampled at various times during the procedure	■ Significant decrease in colony forming unit (CFU) counts at sites around the OR and near the axilla ■ The forced-air warming system filters and the wound edge were found to be sterile	■ There was no mention of the air handling method used in the OR, although it presumably met standards
Moretti B, Larocca AM, Napoli C, et al. Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection? *J Hosp Infect.* 2009;73(1):58-63.	■ 3 ORs	■ 30 total patients undergoing hip arthroplasty (ie, mean procedure time: 90 minutes) ■ 20 patients had a forced-air warming system[c] cover placed, but the study did not indicate where	■ 6 sites including around the OR, near the axilla, and near the wound edge ■ Forced-air warming system filter and output hose were sampled at various times during procedure	■ Although bacterial loads increased at some locations near the OR bed with the use of forced-air warming, the increase was comparable to or lower than the load present at the time the patient was placed on the OR bed	■ Validated air sampling method
Sharp RJ, Chesworth T, Fern ED. Do warming blankets increase bacterial counts in the operating field in a laminar-flow theatre? *J Bone Joint Surg Br.* 2002; 84(4):486-488.	■ Laminar flow ultra-clean-air—ventilated OR	■ 12 different conditions ranging from an empty OR to 4 different volunteers on the OR bed covered with the forced-air warming blanket system[d] with the unit on and off	■ 30 cm from a simulated operating site	■ No detectable airborne contamination was detected at the sample site with any condition	■ This pilot study showed low levels of CFU/m^3 ■ 3 of the 4 volunteers had varying degrees of psoriasis ■ There was no surgical team or traffic in the OR
Tumia N, Ashcroft GP. Convection warmers—a possible source of contamination in	■ 2 ultra-clean-air—ventilated ORs	■ 2 collection periods in an empty OR ■ 4 collection periods during orthopedic procedures	■ Close to the middle of the OR, 1 m off of the floor	■ Nonsignificant increase in CFUs with a forced-air warming system on ($P = .48$)	■ Unknown patient characteristics ■ Unknown where the forced-air warming system

TABLE 3. *(continued)* Summary of Evidence: Bacterial Counts Near or on Patients, Volunteers, or Manikins During Forced-Air Warmer Use

Evidence source[a]	Setting and subjects	Interventions	Sites sampled	Findings	Comments[b]
laminar airflow operating theatres? *J Hosp Infect*. 2002; 52(3):171-174.		■ A forced-air warming system cover was applied to the patient		compared with when it was off	cover was applied ■ Unknown forced-air warming system manufacturer, CFUs, forced-air warming system, forced-air warmer, or OR
Zink RS, Iaizzo PA. Convective warming therapy does not increase the risk of wound contamination in the operating room. *Anesth Analg*. 1993;76(1):50-53.	■ 3 ORs	■ 8 draped volunteers as simulated patients ■ Lower body forced-air warming blanket system[c] ■ 2 study periods: 2 hours forced-air warming system off, 2 hours forced-air warming system on	■ Abdomen	■ No difference in total number of bacterial colonies between two study periods ■ More coagulase negative colonies when the forced-air warming system was off ($P < .05$)	■ OR air handling presumably met standards ■ Volunteers had normal skin and were not taking antibiotics ■ Skin was not prepped ■ There was no surgical team or traffic in the OR

[a] *All studies were Level IV C evidence*
[b] *No mention of sample size calculation or whether forced-air warming systems were maintained according to manufacturer instructions*
[c] *Bair Hugger®*
[d] *Warm Touch™*
Bair Hugger is a registered trademark of the Arizant Healthcare, Eden Prairie, MN. Warm Touch™ is a trademark of Covidien, Mansfield, MA.

Forced-air warmers may interrupt the flow of filtered air toward the area of the wound and may allow dust particles containing pathogenic organisms to come into contact with the wound. To study airflow disturbances, the researchers used different methods:

- Sessler et al[16] and Sharp et al[17] examined airflow using smoke,
- Belani et al[9] and McGovern et al[14] used neutral-buoyancy air bubbles,
- Legg et al[13] and Sessler et al[16] used particle counts, and
- Dasari et al[11] and Legg et al[13] measured air temperature at various heights in the OR.

The methods were well described by the investigators, but only two of the investigators[14,16] described methods to detect airflow disturbances that followed an existing standard[16] or used a previously validated method.[14] None of these studies were conducted when a patient was undergoing a procedure but were performed under controlled conditions, including having no traffic in the OR.

DISCUSSION

The evidence we reviewed does not conclusively indicate that forced-air warmers are a cause of SSIs. The lack of conclusive evidence is mainly

TABLE 4. Summary of Evidence: Unwanted Airflow Disturbances in the OR Caused by the Forced-Air Warmer

Evidence source[a]	Setting, subjects, and intervention	Assessment of airflow disturbance	Findings	Comments[b]
Belani KG, Albrecht M, McGovern PD, Reed M, Nachtsheim C. Patient warming excess heat: the effects on orthopedic operating room ventilation performance. *Anesth Analg*. 2013; 117(2):406-411.	■ Downward displacement in ventilated OR ■ Manikin draped for total knee replacement procedure ■ Forced-air warmer[c] with torso cover, torso conductive fiber blanket,[d] or no warming device ■ Experiment repeated once	■ Neutral-buoyancy detergent bubbles were released under the drape near the head of the manikin and sampled over the surgical site	■ There was an increase in average bubble counts over the surgical site with the forced-air warmer (132.5) compared with the conductive fiber blanket (0.48) ($P < .003$)	■ Motionless anesthesia professional at the head of the OR bed ■ No simulated OR team or traffic ■ Use of bubbles to follow airflow
Dasari KB, Albrecht M, Harper M. Effect of forced-air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia*. 2012;67(3):244-249.	■ Partial-walled, ultra-clean OR ■ Manikin draped for an abdominal procedure ■ Lower body forced-air warmer,[c] over-body conductive fiber blanket,[d] under-body resistive blanket[e]	■ Air temperature measured at 5 heights, including the floor, OR bed, patient, ceiling at 5 locations, and above the surgical site	■ There was a greater increase in temperature over the surgical site with the forced-air warmer: 2.7°C (4.9°F) ($P < .001$) higher than the conductive fabric and 3.6°C (6.5°F) ($P < .001$) higher than the resistive blanket	■ Based on changes in air temperature at various locations, the authors concluded that the forced-air warmer generates convection currents near the surgical site and may produce unwanted airflow disturbances
Legg AJ, Cannon T, Hamer AJ. Do forced air patient-warming devices disrupt unidirectional downward airflow? *J Bone Joint Surg Br*. 2012;94(2): 254-256.	■ Orthopedic OR ■ 1 draped volunteer used to simulate a lower-limb procedure ■ Torso forced-air warmer cover[c] or torso conductive fiber blanket[d]	■ Particle counts (size 0.3, 0.5, 5 µm) 10 cm above the surgical site ■ Air temperature at various locations in the OR	■ Particle counts increased with the forced-air warmer compared with the conductive fiber blanket ($P = .0038$ to .0087)	■ Use of wall extensions to maximize airflow ■ A surgeon with a hood and body exhaust system but no other team members
McGovern PD, Albrecht M, Belani KG, et al. Forced-air warming and ultra-clean ventilation do not mix: an investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics.	■ Laminar flow ultra-clean-air—ventilated OR ■ Draped manikin simulating hip replacement (repeated once) and draped lumbar spinal procedure (not repeated)	■ Neutral-buoyancy detergent bubbles were released near the manikin's head or near the floor ■ The area near the surgical site was observed	■ Air currents with the forced-air warmer on were more toward the surgical site compared with the conductive fabric	■ Single surgeon and anesthesia professional, but no OR traffic

TABLE 4. *(continued)* Summary of Evidence: Unwanted Airflow Disturbances in the OR Caused by the Forced-Air Warmer

Evidence source[a]	Setting, subjects, and intervention	Assessment of airflow disturbance	Findings	Comments[b]
J Bone Joint Surg Br. 2011;93(11):1537-1544.	■ Upper or lower body forced-air warmer[c] cover or torso conductive fabric blanket[d]			
Sessler DI, Olmsted RN, Kuelpmann R. Forced-air warming does not worsen air quality in laminar flow operating rooms. *Anesth Analg*. 2011; 113(6):1416-1421.	■ Two laminar flow ORs ■ Draped volunteer patient ■ Warmed manikins represented surgical team members ■ Forced-air warmer[c] with upper body cover or under-body blanket	■ Smoke with visual tracer	■ There was no impairment in laminar flow and there were no unwanted airflow disturbances with either the forced-air warmer with upper body cover or under-body blanket.	■ No OR traffic
Sharp RJ, Chesworth T, Fern ED. Do warming blankets increase bacterial counts in the operating field in a laminar-flow theatre? *J Bone Joint Surg Br.* 2002;84(4): 486-488.	■ Laminar flow ultra-clean-air–ventilated OR ■ 12 different conditions ranging from empty OR to 4 different volunteers on OR beds covered with forced-air warmer[f] blankets	■ Smoke test	■ There was no significant effect on OR airflow with the forced-air warmer[b] unit on or off	■ No OR traffic

[a] *All studies were Level IV C evidence*
[b] *No mention of sample size calculation or whether forced-air warmers were maintained according to manufacturer instructions*
[c] *Warm Touch™*
[d] *Bair Hugger®*
[e] *Hot Dog Total Access Warming™*
[f] *Inditherm™*
Warm Touch is a trademark of Covidien, Mansfield, MA. Bair Hugger is a registered trademark of Arizant Healthcare, Eden Prairie, MN. Hot Dog Total Access Warming is a trademark of Augustine Temperature Management, Eden Prairie, MN. Inditherm is a registered trademark of Inditherm PLC Corp, Rotherham, England.

because of methodological problems in the investigations, such as a general lack of randomization, methods to determine an adequate sample size, and blinding. Only three[12,14,15] of the 15 investigations[5-19] followed patients who were warmed with a forced-air warmer to determine the incidence of SSI. The majority of the investigations indirectly examined the PICO question by determining whether the forced-air warmer harbored organisms, there was an increase in bacteria on or near the surgical site, or the forced-air warmer caused an unwanted airflow disturbance that could lead to an increase in bacteria entering the wound.

Two[12,15] of the three investigations[12,14,15] that followed subjects on whom a forced-air warmer had been used during surgery did not report an increase in SSIs with forced-air warmer use. These investigators reported there were no SSIs in a small

number of patients who underwent major vascular surgery with prosthetic graft use (ie, 16 patients)[12] or patients who underwent hip arthroplasty (ie, 30 patients)[15] regardless of whether a forced-air warmer was used intraoperatively. Serious methodological problems included the lack of a control group[12] and no description of the length of the follow-up period.[15] A third investigation[14] had a respectable sample size of 1,437 patients undergoing major joint replacement surgery, but more than half of the patients were in the forced-air warmer group. These investigators reported there was a greater risk of an SSI in subjects on whom a forced-air warmer was used intraoperatively (odds ratio, 3.8; $P = .024$). However, potentially serious problems with this study included the disclosure that one or more of the authors had been or was supported by a commercial party that manufactures a competing product.

The remaining three methods indirectly examined the PICO question. With the first indirect method, the findings of five[5-8,10] of the six[5-8,10,12] investigations suggested the forced-air warmer could be harboring bacteria or bacteria-containing particles. Typically researchers took swabs from various locations inside of the forced-air warmer, including the filter, air path, and output hose, and transferred the swabs to culture media manually or by blowing air from the unit directly onto culture plates. The investigators cultured bacteria from these sites and concluded that forced-air warmers could be a cause of SSIs. Two of these investigations[5,6] also concluded that there is a risk of the forced-air warmer emitting particles capable of carrying bacteria. In the investigation indicating that the forced-air warmer did not likely harbor bacteria,[12] the investigators reported there were no bacteria cultured from the output hose and filter. The problems with these investigations[5-8,10,12] were that there was no mention of how the forced-air warmers were maintained and researchers established no causal link between the presence of bacteria in the forced-air warmer and SSIs.

Another group of studies[12,15,17-19] looked at the presence of bacteria near or on volunteers, manikins, or patients when using a forced-air warmer, and none conclusively showed an increase in bacteria. Sharp et al[17] found that there was no airborne contamination regardless of whether a forced-air warmer was used. Zink and Iaizzo[19] found that there was no difference in bacteria counts. Tumia and Ashcroft[18] found an insignificant increase. Huang et al[12] found a significant decrease in colony counts when using a forced-air warmer. The fifth group of investigators, Moretti et al,[15] concluded that although the bacterial loads were increased at some locations when using a forced-air warmer, the increase was no higher than the bacterial load seen at the time the patient was assisted onto the OR bed. None of these investigators reported a conflict of interest.

The final indirect method sought to determine whether forced-air warmers cause unwanted airflow disturbances that encourage bacteria to be blown toward the surgical site. None of these investigations were conducted during actual surgical procedures.[9,11,13,14,16,17] Instead, the researchers used highly controlled simulated

AORN Resources

- Clinical FAQs: Hypothermia. AORN, Inc. *http://www.aorn.org/clinicalfaqs.*
- Periop Mastery Program: Preventing unplanned perioperative hypothermia. AORN, Inc. *http://www.aorn.org/periopmasteryprogram.*
- Recommended practices for the prevention of unplanned perioperative hypothermia. In: *Perioperative Standards and Recommended Practices.* Denver, CO: AORN, Inc; 2013:375-386.

Web site access verified August 5, 2013.

scenarios that did not realistically simulate movement and traffic in the OR. Four[9,11,13,14] of the groups of investigators concluded that forced-air warmers were likely to cause these unwanted airflow disturbances. At least one author in all four investigations had been or was currently supported by a company manufacturing a leading competitor to forced-air warmers. No definitive causal link was established between the airflow disturbances and SSIs. Additionally, one study[16] indicating there was no unwanted airflow disturbance was supported, in part, by a forced-air warmer manufacturer; and one of the investigators received support from a forced-air warmer manufacturer.

NURSING IMPLICATIONS

We found no randomized clinical trials examining whether there is an increase in SSIs in subjects on whom a forced-air warmer is used intraoperatively. All of the studies we appraised for this review had major methodological problems, such as the possibility of an inadequate sample size, lack of blinding, and not maintaining the devices according to the manufacturer's instructions. In the three investigations that followed subjects on whom a forced-air warmer had been used during surgery,[12,14,15] only one[14] concluded there was an increase in SSI with forced-air warmer use; however, not only was there no randomization or blinding in that investigation, there was no control of potentially confounding factors, and it is not known what effect history played on the results because the data were collected during the two-year study period.

RECOMMENDATIONS

Although concerns exist about the potential SSI risk from using forced-air warming units, clinicians should continue to use these devices because they are effective for preventing inadvertent perioperative hypothermia.[20] Clinicians should continue to use these devices so long as they are meticulously maintained according to the manufacturer's instructions, including properly replacing filters. Clinicians should take steps to prevent health care–associated infections from the use of forced-air warmers, just as they should when using any medical device. For instance, personnel should routinely and meticulously clean forced-air warmers with manufacturer-approved products, and these devices should be used strictly according to the manufacturer's instructions. Manufacturers should explore designs that allow for convenient cleaning of the surfaces of the airflow path.

FUTURE RESEARCH

The question of forced-air warmers causing SSIs should be examined in large, multicenter, randomized, controlled trials that are free from potential sources of bias such as funding by competing manufacturers. Observers should be blinded as much as possible and sample sizes should be based on the results of existing, albeit flawed, investigations. Investigators should include similar control and treatment groups with similar antibiotic use and surgical techniques. Until the findings of such rigorous studies are reported, clinicians should continue to use forced-air warmers.

CONCLUSION

Forced-air warming devices are an efficacious method of preventing intraoperative hypothermia and its complications (eg, coagulopathy, SSI).[20] Despite this efficacy, there may be provider hesitation in using these devices because of concerns related to these devices acting as vectors of infection or causing unwanted airflow disturbances that result in SSIs.[2]

Our review uncovered no conclusive evidence that the use of forced-air warmers increases the risk of SSIs. Although there is evidence that bacteria may be harbored on the air path surfaces inside the forced-air warmer, the studies that we appraised failed to establish a causal link between this and an increase in SSIs. The evidence also does not support the concern that use of a forced-air warmer may cause an increase in bacteria near or on the patient or cause unwanted airflow disturbances. These findings confirm the AORN

recommendations that forced-air warming is an effective way to prevent unplanned perioperative hypothermia.[20] AORN

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EXAMINATION

CONTINUING EDUCATION PROGRAM

3.0 CE

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Forced-Air Warming Devices and the Risk of Surgical Site Infections

PURPOSE/GOAL

To provide knowledge specific to the use of forced-air warming systems and surgical site infections.

OBJECTIVES

1. Describe inadvertent perioperative hypothermia.
2. Discuss the use of forced-air warming to maintain normothermia perioperatively.
3. Describe the methodologies used in the studies appraised in this article.
4. Describe the authors' conclusions about the use of forced-air warming systems.

The Examination and Learner Evaluation are printed here for your convenience. To receive continuing education credit, you must complete the Examination and Learner Evaluation online at *http://www.aorn.org/CE*.

QUESTIONS

1. Inadvertent perioperative hyperthermia is the most common thermal disturbance seen in surgical patients.
   a. true *b.* false
2. Reasons for heat loss during operative and invasive procedures include
   1. the patient's exposure to the surgical environment.
   2. the effects of anesthetic agents and medications that interfere with temperature regulation.
   3. redistribution of heat from the core to the periphery of the body.

   a. 1 and 2 *b.* 1 and 3
   c. 2 and 3 *d.* 1, 2, and 3
3. Health care providers often use forced-air warming systems to provide surface warming in the OR because these devices are helpful in maintaining normothermia and preventing hypothermia.
   a. true *b.* false
4. Health care providers are concerned about the use of forced-air warming systems because
   a. of the cost that the health care facility must assume to use the units.
   b. of the potential for increasing the risk of surgical site infections (SSIs).
   c. they are difficult to use and interfere with work flow in the OR.
   d. they are noisy and cause distraction in the OR.
5. What were the methodological concerns the authors found in the studies they reviewed for this article?
   1. Researchers did not describe how they determined sample sizes of forced-air warmers or the number of study participants.

2. Researchers did not indicate whether the forced-air warmers had been maintained according to the manufacturer's instructions.
3. There was no blinding or random allocation of participants to study groups.
4. In some cases, an author of the study was or had been supported by a company that manufactures a competing product to the forced-air warmer.
5. The statistics had been incorrectly calculated.

a. 4 and 5 *b.* 1, 2, and 3
c. 1, 2, 3, and 4 *d.* 1, 2, 3, 4, and 5

6. In the three investigations that followed patients who were warmed intraoperatively for SSIs, it is unknown whether the groups were similar in confounding variables such as

1. obesity.
2. age.
3. incontinence.
4. fitness for surgery.

a. 1 and 2 *b.* 3 and 4
c. 1, 2, and 3 *d.* 1, 3, and 4

7. The first method that researchers used to indirectly examine whether forced-air warmers are likely to cause SSIs included

1. swabbing the interior and exterior of one forced-air warmer.
2. comparing the filtration efficiency of five new forced-air warmer intake filters with five used filters.
3. culturing *Acinetobacter baumannii* from the nares of patients who would be undergoing surgery with a forced-air warmer.
4. swabbing used patient blankets.

a. 1 and 2 *b.* 3 and 4
c. 1, 2, and 3 *d.* 1, 2, 3, and 4

8. The second indirect method used to determine whether forced-air warmers are likely to cause SSIs was to examine bacterial counts

1. close to the middle of the OR.
2. near the surgical site.
3. on the hands of the anesthesia professional.
4. on or near patients or volunteers.

a. 1 and 2 *b.* 3 and 4
c. 1, 2, and 4 *d.* 1, 2, 3, and 4

9. The evidence reviewed for this article did not conclusively indicate that forced-air warmers are a cause of SSIs because of methodological problems with the investigations.

a. true *b.* false

10. Although concerns exist about the potential SSI risk from using forced-air warming units, clinicians should continue to use these devices so long as

1. the units are meticulously cleaned with manufacturer-approved products.
2. personnel properly replace the filters.
3. clinicians take steps to prevent health care–associated infections.
4. the units are used strictly according to the manufacturer's instructions.

a. 1 and 3 *b.* 2 and 4
c. 1, 2, and 3 *d.* 1, 2, 3, and 4

LEARNER EVALUATION

CONTINUING EDUCATION PROGRAM

3.0 CE

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Forced-Air Warming Devices and the Risk of Surgical Site Infections

This evaluation is used to determine the extent to which this continuing education program met your learning needs. Rate the items as described below.

OBJECTIVES

To what extent were the following objectives of this continuing education program achieved?

1. Describe inadvertent perioperative hypothermia.
   Low 1. 2. 3. 4. 5. High
2. Discuss the use of forced-air warming to maintain normothermia perioperatively.
   Low 1. 2. 3. 4. 5. High
3. Describe the methodologies used in the studies appraised in this article.
   Low 1. 2. 3. 4. 5. High
4. Describe the authors' conclusions about the use of forced-air warming systems.
   Low 1. 2. 3. 4. 5. High

CONTENT

5. To what extent did this article increase your knowledge of the subject matter?
   Low 1. 2. 3. 4. 5. High
6. To what extent were your individual objectives met? *Low 1. 2. 3. 4. 5. High*
7. Will you be able to use the information from this article in your work setting? *1. Yes 2. No*
8. Will you change your practice as a result of reading this article? (If yes, answer question #8A. If no, answer question #8B.)

8A. How will you change your practice? *(Select all that apply)*

1. I will provide education to my team regarding why change is needed.
2. I will work with management to change/implement a policy and procedure.
3. I will plan an informational meeting with physicians to seek their input and acceptance of the need for change.
4. I will implement change and evaluate the effect of the change at regular intervals until the change is incorporated as best practice.
5. Other: _____

8B. If you will not change your practice as a result of reading this article, why? *(Select all that apply)*

1. The content of the article is not relevant to my practice.
2. I do not have enough time to teach others about the purpose of the needed change.
3. I do not have management support to make a change.
4. Other: _____

9. Our accrediting body requires that we verify the time you needed to complete the 3.0 continuing education contact hour (180-minute) program: _____

EXHIBIT 4

health. DEVICES

EDITORS' NOTE

Augustine Temperature Management recently published press releases, e-mail blasts, and blog entries on this article, which appeared in the April 2013 issue of ECRI Institute's *Health Devices* journal and is titled "Forced-Air Warming and Surgical Site Infections: Our Review Finds Insufficient Evidence to Support Changes in Current Practice."

ECRI Institute states that it did not participate in or approve of the above-mentioned materials, and warns that they should not be construed as representing our opinion or judgment.

Our views on forced-air warming are explained in our article, and we recommend that readers go here—and nowhere else—to learn what we think.

guidance ARTICLE

FORCED-AIR WARMING AND SURGICAL SITE INFECTIONS

Our Review Finds Insufficient Evidence to Support Changes in Current Practice

Maintaining normothermia during surgery is an important measure in preventing surgical site infections (SSIs). Several technologies are available to accomplish this during surgery, including the popular method of forced-air warming (FAW). Recently, however, some member hospitals have asked us about FAW and whether it might actually contribute to SSIs. Specifically, their questions were focused on whether the use of FAW during surgery (including orthopedic implant surgery) leads to an increased rate of SSIs as compared to the use of other methods of patient warming and, if so, whether such concerns merited discontinuing the use of FAW during surgery. In response to these questions, ECRI Institute has conducted an assessment of the published literature to determine whether the evidence supports a decision not to use FAW.

Based on our assessment, we do not believe that the currently available evidence justifies discontinuing the use of FAW during surgery. This article explains our reason for this judgment.

THE IMPORTANCE OF MAINTAINING NORMOTHERMIA DURING SURGERY

Maintaining normothermia in surgery patients has been reported to significantly lower the risk of postoperative surgical wound infections (Kurz et al. 1996, Melling et al. 2001). Hypothermia triggers vasoconstriction, ultimately resulting in a reduction of the partial pressure of oxygen in tissue. This in turn impairs the body's ability both to fight infection at the wound site and to promote wound healing. Maintenance of body temperature during and after surgery is recommended in practice guidelines by a variety of organizations, including the Centers for Disease Control and Prevention, Guideline for Prevention of Surgical Site Infection, 1999; the American Society of Anesthesiologists, Practice Guidelines for Postanesthetic Care, 2002; the American College of Cardiology/American Heart Association, ACC/AHA 2007 Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery, 2007; and the National Collaborating Centre for Nursing and Supportive Care, The Management of Inadvertent Perioperative Hypothermia in Adults, 2008.

FORCED-AIR WARMING MAY DISTURB AIR PATTERNS IN THE OPERATING ROOM

FAW is a popular method to maintain normothermia during surgery. FAW systems (warming units and blankets) are designed to warm patients by gently blowing warm air onto the skin of the patient via an air blanket. But there are other methods to warm patients during surgery, such as conductive-fabric warmers and water-circulating warmers. The theoretical concern raised with the use of FAW is that air currents created by the system may carry microbes that might contaminate the surgical site.

Some studies have investigated this concern, looking at the impact of FAW on laminar airflow systems—especially the potential disruption of the downward airflow patterns. For example, five studies (Belani et al. 2012, Dasari et al. 2012, Legg et al. 2012, Legg and Hamer 2013, McGovern et al. 2011) demonstrate that the exhaust from FAW units results in thermal currents that rise into the downward ventilation airflow of the laminar airflow systems studied. The disruption of airflow patterns is particularly worrisome in laminar-flow and ultraclean ORs, in which a wide variety of implant surgeries are performed. The argument is that mobilization of contaminated air near the floor or decreased effectiveness of the downward laminar airflow pattern could contribute to an increased rate of SSIs, including prosthetic joint infections (PJIs), compared to when other methods of patient warming are used. This is especially concerning during orthopedic surgeries because contamination of the surgical site may present a greater risk of developing a PJI, which is

UMDNS terms. Warming Units, Patient [17-570] ■ Warming Units, Patient, Circulating-Fluid [17-648] ■ Warming Units, Patient, Conductive Layer [25-785] ■ Warming Units, Patient, Forced-Air [17-950] ■ Warming Units, Patient, Radiant [13-248] ■ Warming Units, Patient, Radiant, Adult [13-249]

harder to treat and resolve than would be the case with SSIs in general. These studies, however, only raise questions about airflow disruptions. Demonstrating that airflow patterns change when FAW is used does not establish that it results in increased bacterial contamination or increased rates of SSI and PJI as compared to use of other methods of patient warming.

WHAT THE EVIDENCE SHOWS

The literature review process we used involves articulating a specific question to answer, creating search strategies for a comprehensive and objective literature search, and identifying inclusion and exclusion criteria that are applied to each study. The studies that meet the inclusion criteria are evaluated for their design and the potential for study bias—specifically, study features that could impact whether the treatment being studied is responsible for the outcomes observed. Studies are then analyzed for the information they contain.

The question we asked was: Do surgical patients whose body temperatures were controlled with FAW systems (when used as intended) have an increased risk of SSIs compared to patients whose body temperatures were controlled by another method? Our inclusion criteria required that the study include a comparison of SSI rates and that it have at least two arms (FAW compared to at least one alternative warming technology), with a minimum of 10 patients (per arm) undergoing surgery. We also required that studies include documentation of body temperature maintenance for all methods and that they report all infections that occurred within a follow-up period of at least 30 days. (Our complete inclusion criteria and the reasoning behind them can be found in "Study Inclusion Criteria" on this page.)

Our search of the published literature identified over 180 studies potentially related to our question. These studies were all eliminated for a variety of reasons. Any study that was not clinical in nature—that is, that did not involve human surgical patients—was excluded. We also eliminated studies that looked at OR contamination when FAW units were used but did not examine SSIs. Granted, some of these studies report increased microbial contamination within FAW units (e.g., Albrecht et al. 2011) or increased particle counts (particles injected into the air, not bacteria) at monitored OR locations when FAW units were being used (Legg et al. 2012, Legg and Hamer 2013). But while studies like these raise questions, they don't establish that an increased risk of SSI exists with FAW compared to other warming technologies. For similar reasons, we excluded studies that solely examined air current patterns that may affect the distribution of microbes.

While we did not find any studies that met all our inclusion criteria, we did identify four studies that came close to meeting our criteria and that examined SSI rates following clinical procedures:

- Two studies—one by Huang et al. (2003) and one by Moretti et al. (2009)—primarily involved assessment of bacterial counts in different locations of the OR and at the surgical wound edges. These studies used slightly different approaches: Huang did cultures at the start and finish of surgery with use of an Augustine Medical Bair Hugger FAW system; Moretti did cultures with and without use of the Bair Hugger FAW system. The authors of the studies reported that no SSIs occurred in any patient in the studies (total of 46 patients combined). *Reason for exclusion:* These studies lacked a comparison of FAW to an alternative warming system.
- A study by Melling et al. (2001) looked at SSI rates in a total of 421 patients who underwent breast, varicose vein, or hernia surgeries. Patients were randomized into three groups: 138 patients with localized warming before surgery, 139 patients with whole-body FAW before surgery, and 139 patients with no warming before surgery

STUDY INCLUSION CRITERIA

The following are the inclusion criteria we used when determining which studies would be included in our analysis. These criteria were developed before the clinical literature review.

- Studies must have enrolled human subjects who underwent surgery involving the creation of a surgical wound. Studies without human subjects do not provide generalizable conclusions.
- Studies must evaluate a forced-air warming system and at least one other means of maintaining a patient's body temperature (with devices used as intended) during surgery. Such comparison studies are needed to determine the extent to which the FAW system is responsible for altering the infection risk compared to other means of maintaining a patient's body temperature, while all other factors in promoting or reducing infection risk are held constant.
- Studies must have data showing that the body temperature of the patient was maintained by both the FAW system and the comparison technology. If the comparison technology or the FAW system was not effective at maintaining body temperature, then this failure rather than other technology differences may be responsible for any differences in infection rate.
- Studies must be randomized controlled trials or nonrandomized comparison studies with at least two treatment arms.
- Studies must have at least 10 patients enrolled per study arm.
- Studies must report the number or rate of surgical site wound infections within 30 days of the surgery.
- Studies must be published in English.
- Studies must be published as full articles in a peer-reviewed journal.

LAWSUIT ALLEGES CONTAMINATION BY FORCED-AIR WARMER

ECRI Institute has learned that in March 2013, a lawsuit was filed against 3M Corporation alleging that a patient sustained a periprosthetic infection while undergoing hip replacement surgery as a result of contaminants being deposited in the surgical site by a 3M Bair Hugger forced-air warmer.

We have reviewed the plaintiff's petition. It does not present any new information that would alter the conclusions we have drawn in this article based on our review of the published literature.

Case information can be found in the press release from the plaintiff's attorneys at www.prweb.com/releases/2013/3/prweb10554160.htm.

(control group). This study compared the Augustine Medical Bair Hugger FAW system to the Augustine Medical Warm-Up. The Warm-Up (which is no longer available for purchase) was a noncontact normothermic wound therapy system designed to provide warmth and humidity in the wound area and was therefore not intended to maintain a patient's body temperature during surgery. The patient warming occurred for a minimum of 30 minutes before surgery. The SSI rate was not significantly different between warming systems (3.6% for Warm-Up, 5.8% for Bair Hugger, p = 0.4), but was significantly lower in warmed patients (5%) versus nonwarmed (14%, p = 0.001). *Reason for exclusion:* There was no comparison of whole-body warming methods used during surgery to maintain normothermia.

▷ A study by McGovern et al. (2011) that examined effects of warming devices on OR ventilation also provided data on PJIs in patients treated by different technologies for maintaining body temperature during surgery. The study reports on 1,437 patients who underwent joint replacement surgery; 1,066 patients had surgery during a period when the hospital used FAW, and 371 had surgery during a period when the hospital switched to using conductive fabric for warming. Data was collected retrospectively. The study reported PJI rates of 3.1% for FAW versus 0.8% for conductive-fabric warming, which was a significant difference (p = 0.024, Wald test) when data was combined for hip and knee surgeries. Based on the study's findings, the authors recommend that FAW not be used in orthopedic surgeries. *Reasons for exclusion:* This study lacked documentation of normothermia during surgery. In addition, the authors reported that both the prophylactic antibiotic regimen and thromboprophylaxis regimens were altered during the study period. Since the two types of warming treatment were not applied concurrently, other treatment differences or changes during the two different time periods may have influenced PJI rates. Other notable limitations of the study are that data was collected retrospectively rather than from a prospective study; the data was from only one hospital; and the authors did not state whether the data was collected from all patients who underwent primary hip and knee replacement surgery during the reported time periods.

Note that no information was provided on what model warming devices were used on patients in the SSI portion of the study, only whether the devices were conductive fabric or FAW. However, in the operating-theater-ventilation portion of the study, a Bair Hugger warming unit with a Model 540 FAW blanket and a Hot Dog brand Model B110 conductive-fabric blanket were used.

CONCLUSIONS

Based on our focused systematic review of the published literature, we believe that there is insufficient evidence to establish that the use of FAW systems leads to an increase in SSIs compared to other warming methods. Although one study (McGovern et al.) presents data that suggests higher PJI rates with use of FAW compared to an alternative warming method, this study has serious limitations such that its findings on PJI rates cannot be considered conclusive. Studies that look at FAW's contribution to OR air contamination and/or airflow disruption raise questions about the technology and its potential impact, but they do not provide sufficient evidence to demonstrate that the use of FAW poses a greater risk of SSIs or PJIs than the use of other warming methods.

Consequently, ECRI Institute does not believe that the currently available evidence justifies discontinuing the use of FAW during surgery. We will continue to monitor this topic through the published literature and will update our recommendation as warranted.

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This report appears in the April 2013 issue of ECRI Institute's monthly Health Devices journal, which is provided to members of ECRI Institute's Health Devices System, Health Devices Gold, and SELECTplus™ programs. Health Devices features comparative, brand-name evaluations of medical devices and systems based on extensive laboratory testing and clinical studies. ECRI Institute's evaluations focus on the safety, performance, efficacy, and human factors design of specific medical devices and technologies.

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EXHIBIT 5

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions

MDL No.
15-2666 (JNE/FLM)

VIDEOTAPED DEPOSITION

OF

MARK ALBRECHT

VOLUME 1

Minneapolis, Minnesota

Friday, October 7th, 2016

Reported by:
Amy L. Larson, RPR
Job No. 112502

ALBRECHT

A. Table 2.
Q. Table 2?
A. Yup.
Q. That says 371, doesn't it?
A. Well, I have 3 and 368, so for conductive fabric.
Q. It's the 368 I'm not getting.
MR. B. GORDON: Three plus --
THE WITNESS: Oh, I'm just -- sorry, I'm giving you the number of successes and failures. Yes, that would be 371 in total.
BY MR. C. GORDON:
Q. By the way, if you -- if you count the number of Wansbeck procedures for HotDog only in Exhibit 10 --
A. Okay.
Q. -- there's only 317. Any idea why the 371 reported in the paper, but 317 --
MR. B. GORDON: Objection --
THE WITNESS: I don't have the raw data.
MR. B. GORDON: Just for the record, we don't know if it's the same data,

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we established that earlier.
MR. C. GORDON: Okay.
BY MR. C. GORDON:
Q. So what's -- what's -- what's the infection rate for 3 out of 293?
A. Well, you have a calculator. It's virtually comparable in this cut of time.
Q. I'm sorry?
A. It's virtually comparable to the other group in this cut of time. So we're at 1.02 percent.
Q. Okay.
A. And for 371 you want? That's where I assume you're going.
Q. Do -- do -- sure, do -- well, you already did that. That's already in the paper.
A. Yeah. So that's .8 percent. All right.
Q. And if you were to do -- count 4 infections in that Bair Hugger period, and we'll say it was 371, what would the infection rate be?
MR. B. GORDON: Objection to the mischaracterization of the data and he's already testified he doesn't know if it's the same data.

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THE WITNESS: So if you want me to tell you what 4 divided by what?
MR. C. GORDON: Well, use 371.
THE WITNESS: Okay. You're at 10 percent. I'm sorry, you're at 1 percent.
MR. C. GORDON: It may be 371.
BY MR. C. GORDON:
Q. So if you had compared the five-month period when Bair Hugger was used with the same antibiotic and same anti-thromboembolism drugs as was used in the seven months of the HotDog period, you're the statistician --
A. Those would not be significant for that cut of time, significantly different.
Q. Not even close to significantly different, right?
A. They would not be significantly different. I don't need to run an analysis to figure that part out.
Q. Why didn't you do that, what we just did?
A. It's an observational study. We plotted the data, we put the concerns in, we talked as a group what to do and we looked at the timeline.

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Q. When you say you plotted the data, there's no way somebody reading that paper could know what the infection rate was during the Bair Hugger only period when the same -- you have the same prophy -- antibiotic and anti-blood clotting regimen was used, right?
MR. B. GORDON: Objection to form, assumes facts not in evidence, misstates the record.
THE WITNESS: As a group, this is where the data analysis landed. We did a bunch of univariate tests on the basic things, we did a transition period on the devices, and we reported it as observational data. This is not a clinical trial with a definitive answer.
BY MR. C. GORDON:
Q. Well, and in response to a reviewer's comments, you noted that there were changes to the antibiotics and thromboprophylaxis during the periods, right?
A. Yes.
Q. But you could have completely eliminated those as confounders by doing what we just

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions

MDL No.
15-2666 (JNE/FLM)

VIDEOTAPED DEPOSITION

OF

MARK ALBRECHT

VOLUME 2

Minneapolis, Minnesota

Saturday, November 12th, 2016

Reported by:
Amy L. Larson, RPR
Job No. 115236

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THE WITNESS: It depends on what you define as "cause." It was associated with.
BY MR. COREY GORDON:
Q. In your professional experience as a statistician dealing in the field of medical and biological issues, is there any difference to you between something that's associated with and something that causes?
MR. ASSAAD: Objection to form.
THE WITNESS: Yes, there is a difference between association and cause, and causation.
BY MR. COREY GORDON:
Q. And you were one of the coauthors of the McGovern study that's being characterized here. Do you agree with the characterization that your study found that forced-air warming caused a 3.8 times increase in deep joint infection rates?
MR. ASSAAD: Objection to form.
THE WITNESS: I would agree that it's associated with the 3.8 times increase, that's what the study would say.

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BY MR. COREY GORDON:
Q. So you would -- you would -- you would agree, then, that you did not conclude or show that it caused a 3.8 times increase in deep joint infection rates?
MR. ASSAAD: Objection to form.
THE WITNESS: We did not prove causation.
BY MR. COREY GORDON:
Q. So -- and you would agree that this statement by Dr. Augustine is a mischaracterization of the study on which you were a coauthor?
MR. ASSAAD: Objection to form.
BY MR. COREY GORDON:
Q. Correct?
A. It's speculation, because it didn't use the exact word "causation." If I were to look for association versus causation, I'd need to have that word, if you want me to be frank with you on statistical terms.
Q. I just want you to be frank with me on whether you think that Dr. Augustine accurately characterized your study when he said, "Forced-air warming was shown to cause

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a 3.8 times increase in deep joint infection rates."
MR. ASSAAD: Objection to form, asked and answered.
BY MR. COREY GORDON:
Q. Is that a correct characterization or not?
MR. ASSAAD: Same objection.
THE WITNESS: It depends on the context. It's not causation, it's association.
MR. COREY GORDON: Okay.
BY MR. COREY GORDON:
Q. I can't give you any more context on what Dr. Augustine's words are here. "Forced-air warming was shown to cause a 3.8 times increase in deep joint infection rates," is that, in your view as one of the coauthors of the study, accurate or not accurate?
MR. ASSAAD: Objection to the form, asked and answered. Object to the preamble.
MR. COREY GORDON: But you've got to move to strike it, Gabriel.
MR. ASSAAD: I'm not moving to

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strike it, I'm just objecting to it.
THE WITNESS: "More importantly, forced-air warming was shown to associate with a 3.8 times increase in deep joint infection rates," that I would agree with. With what's written there, it seems a little -- I would have to say probably not, no.
BY MR. COREY GORDON:
Q. And -- and, in fact, you recall the exercise we went through at some length in your first deposition?
A. Oh, yes.
Q. The association between forced-air warming and infection rates maybe would not be very strong if you factored out the deep vein thrombosis treatment change?
A. If you had reason to believe --
MR. ASSAAD: Objection; asked and answered.
THE WITNESS: If you had reason to believe that the standard of care was lowered for those patients in those areas, maybe. So it wasn't no thrombosis agent versus

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THE VIDEOGRAPHER: So both volumes, we're at 6:53 on record.

MS. ZIMMERMAN: Thanks.

(Whereupon, Exhibit 36 was marked for identification.)

BY MR. COREY GORDON:

Q. I'm going to show you Exhibit 36. It's an exchange of e-mails between you and Professor Nachtsheim, correct?

A. Okay. Yes, it is.

Q. Okay. And I want to direct your attention to the second page where Professor Nachtsheim says to you, "Hard to disagree with the last quote where the guys said that the data are compelling, but they don't prove the link to infections in practice and a clinical trial would be needed to do that, do you agree," question mark. Did I read that correctly?

A. I will read it just to make sure. "Interesting article. Even though they were petty hard on Scott, hard to disagree with the last quote where the guy said that the data are compelling, but they don't provide the link to infections in practice and that

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clinical trial would be needed to do that; do you agree?"

Q. You said, "Provide." I think it says, "Prove."

A. My apologies.

Q. And your response was, "Yes, I do agree with that." And, in fact, why don't you read your response.

A. Okay. "Yeah, I do agree with that. Personally, I don't think it's a good idea to use forced-air warming in implant cases sensitive to airborne contamination based off" -- "based upon its effects on clean airflow occurrence over the surgical site, but we do not have conclusive proof at this time that increased infections are the result of such ventilation disruption, nor are we likely to ever have such proof. Such a trial would involve upwards of thousands of patients and carry a $2 million price tag, at minimum cost of 2,000 a patient I'm guessing. This is one of those things where we can step close to the line, and we do have important information to present that clinicians should

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be aware of, but we also have to be careful that we do not state claims regarding proof of infection reduction. Unfortunately, Scott likes to say that he's convinced of such a relationship, even though I tell him it is unsupported and I do not agree. Well, that is the difference between research and marketing. However, he knows better than to make such statements in journal articles and does not pressure me/us to do so. As such, I figure he can do as he pleases without harm as long as he respects the research boundaries, which he has to date."

MR. COREY GORDON: Okay. Here's the deal. I have probably about two hours more of questioning for you. I know I'm bumping up to the seven-hour limit. I -- I would ask you to let me go ahead and finish up. If you want to say no, you know, absent special provisions from the court, it's a maximum of seven hours, that -- that is your privilege, and I will -- I will likely ask the -- the court to give some -- give me some additional time. They're going to have

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questions for you and, you know, I'm sure they don't want me to go on any further.

So, you know, I'm going to -- it's probably partially up to you. But even if you say, yeah, why don't you just go ahead and finish with me, they're probably going to object.

MR. ASSAAD: We --

MS. ZIMMERMAN: Should we go off the record for a minute?

MR. ASSAAD: Yeah, let's go off the record.

THE VIDEOGRAPHER: We're going off the record at 11:26 a.m.

(Whereupon, a brief recess was taken.)

THE VIDEOGRAPHER: We're going back on the record at 11:31 a.m.

MR. ASSAAD: It's my understanding that the seven hours are up at this time, give or take a couple of minutes. I don't know if Mr. Gordon has any questions.

We definitely want to ask -- we definitely object to defense counsel moving

EXHIBIT 6

ANESTHESIA & ANALGESIA

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Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room

Robert S. Zink, MD, and Paul A. Iaizzo, PhD

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Although convective warming therapy is effective in preventing hypothermia in anesthetized patients, little is known concerning the potential risks of its use. Hence, this balanced cross-over study was designed to determine if the use of convective warming therapy increased the risk of wound contamination. For 4 h, eight healthy male volunteers (aged 20–25 yr) lay supine on an operating room table with their lower bodies and legs covered with a warming cover and sterile surgical drape. The convective warming therapy was administered for 2 h. The other 2 h served as the control. In each session, culture plates were placed directly on the subject's abdomen through an opening in the drape. Tympanic membrane and leg skin temperatures were significantly higher with active warming. No significant differences in the number of bacterial colonies were observed between the two study periods. It was concluded that convective warming therapy, when appropriately applied, does not increase the risk for airborne bacterial wound contamination in the operating room.

(Anesth Analg 1993;76:50–3)

Wound infection is an important postsurgical problem. A wound infection complicates the recovery from an operation, can prolong the hospital stay, and substantially increases the cost of care. It has been estimated that a postoperative wound infection can increase the patient's stay approximately 6–14 days (1,2). In one study, decreasing the postoperative infection rate from 4.2% to 1.6% saved that institution approximately $750,000 over a 5-yr period (3). Reported rates for wound infection can range from 1% to 5% for "clean" cases and up to 6% for all cases (4,5).

Following studies in which the settling of bacteria onto sedimentation plates in the operating room were observed, specific guidelines for the rate of air turnover in the operating room were made by the Centers for Disease Control (5). A turnover rate of 20 exchanges per hour is considered necessary to minimize this potential source of contamination (6). With the recent advent of using convective based warming and/or cooling devices with airflows up to 15 m^3/min in close proximity to surgical patients, the potential risk for airborne bacterial contamination warranted reassessment. The present study was undertaken to test the hypothesis that the use of such therapy would be unlikely to increase a patient's risk for wound contamination during surgery.

Methods

This study was approved by the University of Minnesota Human Subjects Committee and was performed in three different operating rooms at the University of Minnesota Hospital during a 3-wk period. Eight healthy male volunteers (aged 20–25 yr), free of any cutaneous or systemic disease, and not having taken any antibiotics within a month before the study, gave informed consent for participation. Each subject was instructed to lay supine and relatively motionless on an operating room table for two consecutive 2-h trials. Their lower body and legs were covered with an operating room convection warming cover (Augustine Medical Inc., Eden Prairie, MN) with the adhesive edge securely applied at the level of the umbilicus. A sterile surgical drape with a chest opening was placed over the subject from the feet to the neck. The subject's skin was not surgically prepared or disinfected in any way. All subjects wore briefs and a surgical mask throughout the study.

The subjects inserted their own tympanic temperature probe (Mon-a-Therm Inc., St. Louis, MO) into their right ears. The wires were then secured to the patients by adhesive tape to prevent accidental removal. Self-adhesive skin temperature probes (Mon-a-Therm Inc.) were applied to the mid-thigh and the abdomen below the sternum. Temperatures were re-

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0003–2999/93/$5.00

Table 1. Airborne Bacteria Detected During 2-h Trial Periods With and Without the Use of Convective Warming Therapy: Five Different Bacterial Types Were Cultured

Subject and culture type†		Control (no therapy)	Convective warming therapy
1	SBA	α-Streptococcus: 2 colonies Coagulase (–)-Staph: 1 colony	*Sterile
	Mac	Sterile	Sterile
	CNA	Coagulase (–)-Staph: 1 colony	Coagulase (–)-Staph: 1 colony
2	SBA	*Coagulase (–)-Staph: 2 colonies Bacillus: 1 colony	Coagulase (–)-Staph: 3 colonies
	Mac	Sterile	Sterile
	CNA	Coagulase (–)-Staph: 1 colony	Sterile
3	SBA	Coagulase (–)-Staph: 3 colonies	*Coagulase (–)-Staph: 4 colonies Micrococcus: 1 colony
	Mac	Sterile	Sterile
	CNA	Coagulase (–)-Staph: 2 colonies	Sterile
4	SBA	Coagulase (–)-Staph: 2 colonies Corynebacteria: 2 colonies	*Coagulase (–)-Staph: 2 colonies Micrococcus: 1 colony
	Mac	Sterile	Sterile
	CNA	Coagulase (–)-Staph: 2 colonies Corynebacteria: 1 colony	Coagulase (–)-Staph: 1 colony
5	SBA	*Coagulase (–)-Staph: 15 colonies Corynebacteria: 1 colony	Coagulase (–)-Staph: 2 colonies
	Mac	Sterile	Sterile
	CNA	Coagulase (–)-Staph: 15 colonies Corynebacteria: 1 colony	Sterile
6	SBA	*Coagulase ( )-Staph: 2 colonies	Coagulase (–)-Staph: 1 colony Corynebacteria: 1 colony
	Mac	Sterile	Sterile
	CNA	Sterile	Coagulase (–)-Staph: 1 colony
7	SBA	Coagulase (–)-Staph: 2 colonies	*Corynebacteria: 1 colony
	Mac	Sterile	Sterile
	CNA	Sterile	Coagulase (–)-Staph: 1 colony
8	SBA	*Coagulase (–)-Staph: 1 colony	Sterile
	MAC	Sterile	Sterile
	CNA	Sterile	Sterile

SBA = sheep blood agar; Mac = MacConkey; CNA = colistin-nalidixic acid; Staph = staphylococcus.
* = first set of data for that individual.

corded at 15-min intervals, and arterial blood pressures and heart rates were recorded using a Colin BP8800 automated blood pressure monitor (Colin Electronics Co. Ltd.) at 30-min intervals throughout the study. Three different types of bacterial culture plates were fastened to each subject's abdomen with double-sided tape at the start of each trial period, generating six plates per subject. The plate types were: 1) sheep blood agar (a nonspecific medium; six or more bacteria types may be detected); 2) MacConkey agar (a primary isolation medium for recovery of aerobic and anaerobic Gram-negative bacteria); and 3) Colistin-Nalidixic Acid agar (inhibitory to Gram-positive organisms; six or more bacteria types may be detected). Subjects were randomly divided into two groups. One had the convective cover in place, but not inflated for the first 2-h period. The blowers (Bair Hugger Model 500, Augustine Medical, Inc.) were operational on the medium setting for the latter 2-h period. The other group had their trial periods reversed: i.e., the blowers were on initially. In this design, each subject served as his own control. A blower setting of medium corresponds to an airflow of 10.7 m^3/min at a temperature of 38 ± 3°C. At the end of the study period, the plates were cultured at 35°C for 48 h and read for the presence and type of bacteria.

Statistical significance of the temperature, heart rate, and blood pressure data was determined using Student's *t*-test, whereas the bacterial culture data were analyzed by a two-way analysis of variance. A P value < 0.05 was considered significant.

Results

No significant difference in the total number of bacterial colonies isolated on culture plates was observed

Table 2. Arterial Blood Pressure, Heart Rate, and Temperature Data at Selected Time Points for the Subjects in Each Study Group

Control-therapy subjects 2, 5, 6, 8	Time zero	1 h of control	End of control	1 h of warming	End of warming
Mean BP (mm Hg)	98 ± 6.2	96 ± 3.3	95 ± 6.4	93 ± 3.1	98 ± 2.6
HR (beats/min)	72 ± 8.6	66 ± 7.5	66 ± 8.3	63 ± 6.7	70 ± 11.3
Tympanic temp (°C)	37.3 ± 0.4	36.7 ± 0.2	36.7 ± 0.3	36.8 ± 0.3	36.8 ± 0.2
Thigh temp (°C)	33.5 ± 1.0	35.2 ± 1.4	35.1 ± 1.4	37.1 ± 0.6	37.1 ± 0.4
Abdominal temp (°C)	33.7 ± 1.4	33.2 ± 1.2	32.2 ± 1.7	32.1 ± 1.9	32.9 ± 1.1
Therapy-control subjects 1, 3, 4, 7	**Time zero**	**1 h of warming**	**End of warming**	**1 h of control**	**End of control**
Mean BP (mm Hg)	99 ± 5.0	94 ± 7.3	93 ± 7.8	95 ± 7.5	94 ± 7.7
HR (beats/min)	77 ± 7.0	70 ± 7.1	69 ± 10.4	64 ± 5.1	71 ± 1.5
Tympanic temp (°C)	36.9 ± 0.2	36.8 ± 0.2	36.7 ± 0.2	36.5 ± 0.3	36.5 ± 0.3
Thigh temp (°C)	34.5 ± 1.3	33.0 ± 1.3	37.0 ± 0.2	32.1 ± 0.6	35.3 ± 0.3
Abdominal temp (°C)	34.0 ± 0.7	36.9 ± 0.2	33.1 ± 0.8	35.2 ± 0.3	32.1 ± 0.8

BP = blood pressure; HR = heart rate; temp = temperature.

between the two study periods. Five types of bacteria were isolated from the control plates: coagulase (–)-staphylococcus, corynebacteria, micrococcus, α-streptococcus, and bacillus. Only the first three types were isolated from the study plates (Table 1). The number of colonies of coagulase (–)-staphylococcus was significantly different between the groups, the control group having more colonies than the study group ($P < 0.05$).

There was no difference in arterial blood pressure or heart rate between the two trial periods (with and without active warming) or between the two groups (i.e., warming either initially or following a control period). In each group, there was a tendency for the heart rate to increase toward the end of each period, possibly in anticipation of completion (Table 2). Similarly, the temperature of the exposed skin of the abdomen in the region of culture dish placement was not significantly different between groups (Table 2). The averaged tympanic membrane temperatures for the subjects in the control therapy group decreased initially then rose slightly during warming, whereas temperatures of the other subjects decreased slightly during both warming and control (Table 2). Pooled tympanic membrane temperature data from both groups are presented in Figure 1. As expected, thigh skin temperatures were significantly higher during warming ($P < 0.05$). No subject reported feeling uncomfortably cold or began to shiver during either part of the study.

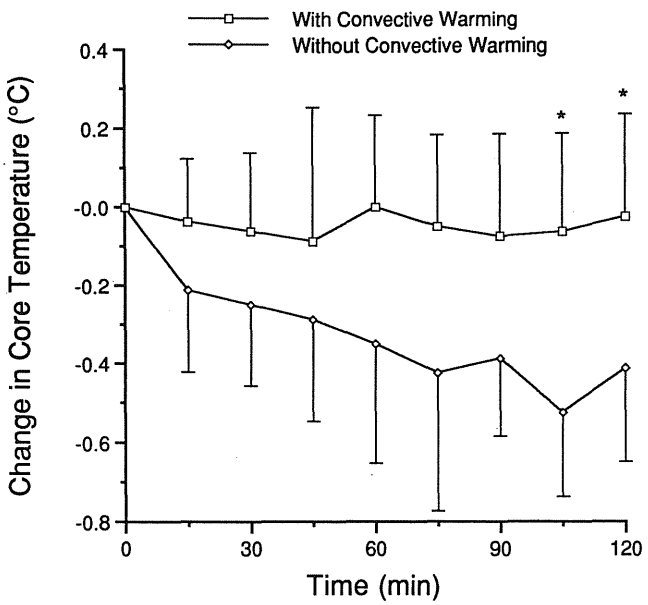

Figure 1. The effects of convective warming on core temperature (tympanic). The temperature data were normalized (per individual), and data for all subjects were pooled. With active warming, the core temperature was stable, whereas without warming a significant decrease was noted by the end of the control periods. * Significant difference ($P < 0.05$).

Discussion

With the potential for convective-based warming devices to become commonplace in the operating room, it is important to assess their potential contribution to airborne bacterial contamination. The use of these devices raises some concern because they can contribute high air flows in close proximity to the patient. The relation between air movement and aerosolization of bacteria has been studied for years. The most significant sources of airborne bacteria are the patient (7), the surgical team (8), and even personnel in the corridors surrounding the operating room suite (6). Methods studied to combat this threat include "ultra-clean" laminar air flow rooms (8) and clothing with small pore size to limit the shedding of bacteria-laden skin particles (9).

This study was designed to evaluate the settling of bacteria at a simulated surgical site, an obvious prerequisite for the development of a wound infection via airborne bacteria. This design could be considered as simulating a "worst case scenario" because the subject's skin was not disinfected in any way. In addition, the awake subjects were free to move their upper extremities and talk, thus possibly contributing to the number of airborne particles. We hypothesize that if the subjects would have received a full antibacterial treatment prior to the study, the number of colonies cultured on the plates might have been fewer. Although there were no surgical personnel in the operating room suite, the investigators (who were not scrubbed) were frequently moving in and out of the room.

The bacteria most commonly detected in the present study was coagulase (–)-staphylococcus, an organism commonly associated with aerosolized contamination and a leading cause of postoperative wound infections (7). Of surprise was the absence of *Staphylococcus aureas*, which is among the most common pathogens isolated in studies of serious wound contamination and infection (8). A possible explanation for this difference between studies could be in the product design: the floor mounted blower used in the present study is designed with a 0.2-μm filter at the air intake, this size being much smaller than the average size of bacteria-carrying particles (20 μm) (9). In addition, the adhesive strip on the warming cover is applied at the waist, serving to direct the flow of air away from the surgical site and the surgical personnel.

As predicted, the decrease in core temperature observed in these unanesthetized subjects was much less than that commonly seen in anesthetized patients placed in a similar operating room environment (i.e., 1°C) (10,11). Anesthetized patients are considered to have disruption within their thermoregulatory mechanisms as well as anesthetic-induced cutaneous vasodilatation (12).

In conclusion, convective warming therapy, when properly applied to direct the flow of air away from the surgical site, does not increase the risk for wound contamination in the operating room.

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EXHIBIT 7

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Research

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The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk?

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Abstract

Introduction Use of the Bair Hugger forced-air patient warming system during prolonged abdominal vascular surgery may lead to increased bacterial contamination of the surgical field by mobilization of the patient's skin flora.

Methods This possibility was studied by analyzing bacterial content in air and wound specimens collected during surgery in 16 patients undergoing abdominal vascular prosthetic graft insertion procedures, using the Bair Hugger patient warming system. The bacterial colony counts from the beginning and the end of surgery were compared, and the data analyzed using the Wilcoxon matched pairs test.

Results The results showed not only that there was no increase in bacterial counts at the study sites, but also that there was a decrease ($P<0.01$) in air bacterial content around the patient and in the operating theatre after prolonged use of the patient warmer. No wound or graft infections occurred.

Conclusion The use of this warming system does not lead to increased bacterial contamination of the operating theatre atmosphere, and it is unlikely to affect the surgical field adversely.

Keywords air microbiology, human, intraoperative care, operating rooms, surgical wound infection

Introduction

Forced-air patient warming systems, such as Bair Hugger (Augustine Medical Inc., Eden Prairie, MN, USA), were developed in the 1980s and are acknowledged as being the most clinically effective patient warming modality [1,2]. The advantages of avoiding hypothermia for patients undergoing major surgical procedures are well established, and include decreased blood loss (with consequent reduction in blood product use) [3], wound infection [4], duration of intensive care and hospital stay [5,6] and cardiac ischaemia [7,8], and increased survival [6,9,10]. However, a potential disadvantage is the risk for bacterial contamination of the operating theatre environment. Prolonged exposure of the patient to the exhaust of the warming blanket could potentially mobilize their resident skin organisms into the theatre atmosphere, and thence into the surgical field, possibly increasing the risk for prosthetic material infection. This has not previously been investigated.

We studied whether use of the Bair Hugger patient warming system increased bacterial contamination of the operating theatre and the surgical wound during prolonged surgery.

Methods

Sixteen consecutive patients undergoing aortic surgery with prosthetic graft insertion were prospectively studied. All vas-

cular surgery was performed in a standard positive pressure theatre. The Bair Hugger upper body blanket (model 522) was used for all patients. Bacteria sampling sites are shown in Fig. 1. Air samples were taken using standard techniques from the theatre atmosphere (sites A1–A3) and around the axillae (sites B1 and B2), where the exhaust air emerged, using the Biotest RCS centrifugal air sampler and Biotest Hycon TC agar strips (Biotest UK Ltd, Solihull, West Midlands, UK). A total of 160 l of air was sampled in 4 min from each of these sites. Sterile swabs were used to take specimens from the warming unit and hose (site C) and immediately plated onto standard blood agar culture media. Further specimens were taken from the wound edges with touch plates of blood agar (site D). Two readings were taken from each site, one when the warming blanket was first applied at the start of the operation and again at the end of the operation. All the culture media were then incubated at 36°C for 24 hours. The number of bacterial colonies visible to the naked eye on each of the agar strips and culture plates were then counted by hand and recorded.

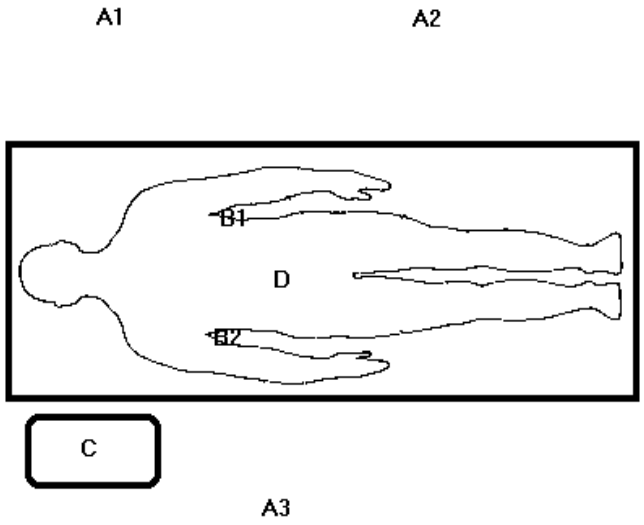
The duration of the operation was recorded. There were nine staff circulating in the operating theatre: three surgeons, two anaesthetists, one operating department assistant and three nurses. All patients had three doses of intravenous antibiotics perioperatively. The data were analyzed using the Wilcoxon matched pairs test [11].

Results

Twelve male and four female patients were included in the present study. Their mean age was 72.5 years (range 60–86 years). The mean duration of use of the warming blanket was 234 min (range 180–270 min). From each site, the number of bacterial colonies at the start of surgery was compared with that at the end of the operation.

Results are shown in Tables 1 and 2. All operating theatre air specimens (sites A1–A3) exhibited a decrease in colony counts at the end of surgery (mean reduction 36.4%). The exhaust air (sites B1 and B2) colony counts also decreased at the end of surgery, although the size of the reduction was much less (mean reduction 9.5%). In the Wilcoxon matched pairs test, the test statistic T equalled 0, because the rank difference was negative for all specimens from sites A1–A3, and B1 and B2. This indicates that there was a significant decrease in the colony counts at the end of surgery as compared with the beginning ($P<0.01$). All filter (site C) and wound specimens (site D) were sterile.

Figure 1



Sampling sites. A1–A3, room air; B1 and B2, exhaust from under drapes; C, hose and filter of warming unit; D, wound.

None of the patients developed postoperative wound or prosthetic infections during a 6-month follow-up period.

In the present study bacteria were not typed; only the absolute numbers of colonies cultured were counted. Typing was to be done only if there was an increase in colony counts at the end of surgery, and this did not occur in any of the patients studied.

Discussion

As indicated above, the benefits of maintaining normothermia in surgical patients is well documented. It has been shown

Table 1

Comparison of the mean number of colonies

	Mean number of colonies		
Site (see Fig. 1)	Start of operation	End of operation	Mean change
Operating room air (A1–A3)	112.9 (82–296)	71.7 (62–162)	36.4% reduction
Exhaust (B1 and B2)	31.6 (22–90)	28.6 (15–86)	9.5% reduction
Hose/filter (C)	0	0	–
Wound (D)	0	0	–

Values are expressed as mean (range).

Table 2

Comparison of colony numbers

	Number of bacterial colonies at different sites (see Fig. 1)					
	Room air (A1–A3)			Exhaust (B1 and B2)		
Patient number	Pre	Post	Change	Pre	Post	Change
1	112	71	−41	29	27	−2
2	102	62	−40	32	30	−2
3	99	70	−29	24	22	−2
4	98	73	−25	22	21	−1
5	97	62	−35	27	25	−2
6	120	67	−53	25	23	−2
7	89	63	−26	37	25	−12
8	129	73	−56	24	22	−2
9	124	68	−56	27	23	−4
10	296	141	−155	90	86	−4
11	98	70	−28	30	24	−6
12	82	63	−19	31	30	−1
13	96	66	−30	22	20	−2
14	91	64	−27	28	25	−3
15	90	68	−22	31	29	−2
16	83	66	−17	27	26	−1

that the warming equipment itself does not cause bacterial dispersal [12] but the role of patient flora was not investigated and the study was not conducted in a true surgical setting. This remained a concern in our unit, especially because some bacteria in wound infections originated from the patients' skin [13]. The present study did not show any increase in the mobilization and dispersal of patient resident skin organisms. The exhaust air from beneath the surgical drapes, which had passed over the patient's skin, showed a decrease in the number of bacterial counts at the end of surgery, and this demonstrated that there was no increase in air contamination associated with the Bair Hugger patient warming system. Furthermore, it indicated that the warm air stream did not force circulation of the patients' skin organisms. If the Bair Hugger were affecting the atmosphere adversely, then the room air counts would also be expected to increase rather than decrease. In fact, the colony numbers in room air and system exhaust were reduced and this was consistent.

Although the study was not designed to evaluate other causes of bacterial presence in the operating theatre, we feel that the higher count at the beginning of surgery in room air may be due to the unrestricted movement of personnel in and out of the operating room, with opening and closing of doors, leading to increased air flow and turbulence. Toward the end of surgery, movement of staff is much less and this may explain the fall in bacterial counts seen as the air turbulence decreases [14,15].

Conclusion

We conclude that the use of the Bair Hugger patient warming system during prolonged abdominal surgery does not lead to increased bacterial contamination of the operating theatre atmosphere, and it is therefore unlikely to cause contamination of the surgical field.

Competing interests

None declared.

Key messages

- Forced-air warming does not force patient's resident skin organisms into and contaminate the operating theatre atmosphere
- Such systems are unlikely to increase the incidence of wound and prosthetic infections

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EXHIBIT 8

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Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection?

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KEYWORDS
Bair Hugger system;
Nosocomial infection;
Orthopaedic surgery;
Thermoregulation

Summary Various reliable body heat-regulating systems have been designed and developed with the aim of maintaining an adequate body temperature in the course of major surgery. This is crucial to avoid the onset of potentially severe complications that are especially serious in elderly and debilitated subjects. Among these systems, the Bair Hugger blanket has demonstrated excellent efficacy. However, some reports in the literature have suggested that the use of such devices can increase the risk of nosocomial infections, particularly surgical wound infections. The aim of this study was to assess the risk of contamination of the surgical site correlated to the use of the Bair Hugger blanket during hip replacement surgery. To this end, the level of bacterial contamination of the air in the operating theatre was quantified with and without the use of the Bair Hugger, during the course of 30 total non-cemented hip implants performed in patients with osteoarthritis. Sampling was done both in the empty theatre and during surgical procedures, in different zones around the operating table and on the patient's body surface. Statistical analysis of the results demonstrated that the Bair Hugger system does not pose a real risk for nosocomial infections, whereas it does offer the advantage of preventing the potentially very severe consequences of hypothermia during major orthopaedic surgery. In addition, monitoring patients over the six months following the

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operation allowed us to exclude a later manifestation of a nosocomial infection.

Introduction

A number of studies have demonstrated that a drop in body temperature, especially during major surgery, can cause potentially dangerous complications, particularly in the elderly and debilitated, or in those with pre-existing disease.[1,2] Nosocomial infections are a particular problem, adversely affecting the postoperative course in terms of patient morbidity, longer hospital stay and higher associated costs for the healthcare facility.[3–7]

To guarantee the maintenance of an adequate body temperature, a number of different regulation systems with proven efficacy have been designed and developed.[8,9] Among these is the Bair Hugger system (Augustine Medical Inc., Eden Prairie, MN, USA), that consists of a temperature management unit comprising a heat generator, a blower to circulate the heated air and a temperature control system equipped with various sensors. This unit is connected by a rubber tube to a blanket that is heated by circulating warm air, thus maintaining the surface temperature of the body underneath it within a physiological range.[10,11]

Some reports in the literature, however, have suggested that such body-warming devices could themselves pose a risk factor for perioperative nosocomial infections, especially at the surgical wound site.[12–16] The aim of this study was to assess the infective risk associated with the use of such devices during hip replacement surgery. We studied the levels of bacterial contamination in the operating theatre potentially associated with the use of the Bair Hugger.

Methods

To assess the infective risk potentially correlated with the use of the Bair Hugger body-warming system, the levels of bacterial contamination present in the air in the operating theatre were monitored with and without the use of the forced-air warming blanket.[17,18]

The air sampler used was an Active Surface Air System (SAS; Aquaria, s.r.l, Italy), a single plate sampling system that directs a constant flow of air on to an agar plate, and which meets the ISO 14698-1 standard. The efficacy of the device is evaluated on the basis of the cut-off size (d_{50}), i.e. the minimum diameter of the particles selected by the sampler. Pasquarella *et al.*, in a recent review, reported the different cut-off size of some air samplers as ranging from 0.58 μm (Andersen Cascade Impactor, stage n.6) to 7.5 μm (Reuter Centrifugal Sampler).[19] The SAS has a d_{50} of 1.5 μm, implying a good level of efficacy; it is particularly suitable for studying air where there may be low concentrations of organisms, such as in hospital environments.[19–22] Moreover, despite the greater efficacy of the Andersen sampler, Morris *et al.* recommended the use of the SAS device because of its being so practical and reliable when used in epidemiological studies and during outbreak investigations in hospital environments.[23]

The air was blown at a flow rate of about 90 L/min onto 55 mm Petri dishes containing Plate Count Agar culture medium to quantify the total bacterial load; Mannitol salt agar (MSA), Wurtz and Sabouraud agars (all agars supplied by Biolife Italiana s.r.l, Milan, Italy) to make a qualitative assessment of any organisms found. After sampling, the plates were incubated at 36 °C in air for 48 h before counting and identifying any potentially pathogenic micro-organisms.

The bacterial counts were expressed as cfu/m^3 (colony-forming units per square metre of air).

Sampling was done during total non-cemented hip implantations performed on 30 female patients with osteoarthritis, with a mean age of 64 years (range: 58–71). All procedures were performed at the Bari University Hospital, Italy. In 20 of the subjects, a Bair Hugger blanket was placed on the operative couch, and used for an average period of about 90 min. As suggested by Huang *et al.*, sampling was done for all the procedures, both at rest, when the theatres were empty and not being used, and under operational conditions, in three different points (A1, A2 and A3) around the operating table, as shown in Figure 1 and at two different times (prior to patient placement on the table, and at the start of the procedure).[13]

In the 20 cases in which the Bair Hugger was used, sampling was also carried out during the course of the operating procedures. For these subjects, environmental sampling was done in

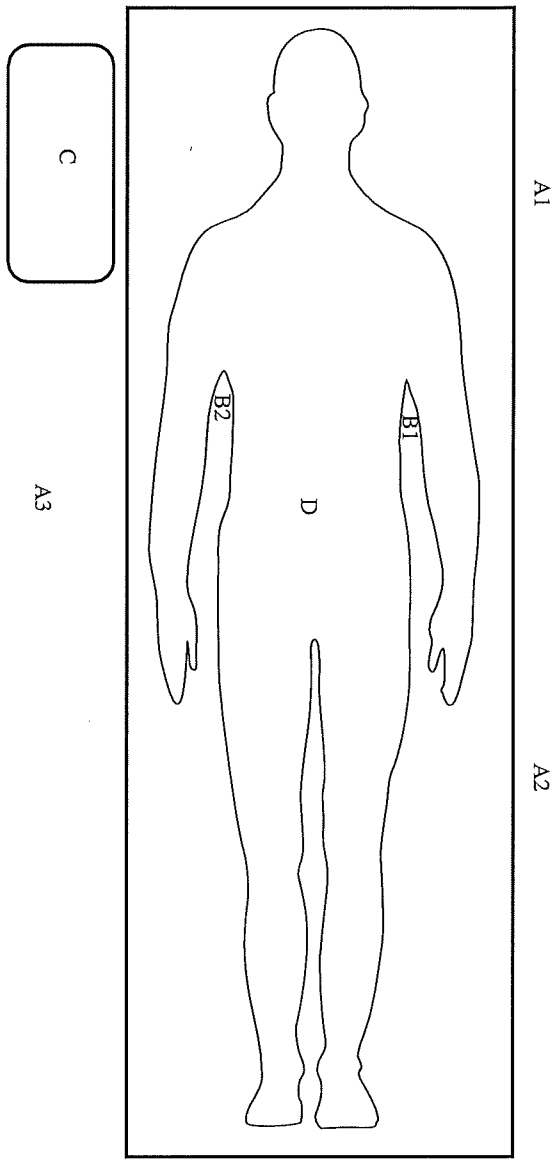

Figure 1 Air sampling points. (Redrawn from Huang *et al.*[13] by kind permission.)

the zones around the axillae, where the air emerged (B1 and B2, Figure 1) and in the zone around the blower (tube and heating unit filter). Samples were also taken from the patient using sterile buffers on the skin surface to be incised, before disinfecting the skin, and in the same way on the same area at the end of the procedure.

To reveal any significant variations among the three sampling points of the operative site (A1, A2, A3, Figure 1) analysis of variance was performed; the alpha level of significance was set at $P < 0.05$. Statistical analysis of the environmental samples was done using the SAS statistical software package (SAS Institute Inc., Carolina, USA). All patients were monitored for a further six months to check for late onset of nosocomial infection.

Results

Under the at-rest conditions in the empty theatres, no significant differences were observed among the mean values of the bacterial loads measured at the three different points around the operative site (A1 = 17.8 ± 14.5 cfu/m^3; A2 = 19.4 ± 17.5 cfu/m^3; A3 = 19.2 ± 17.7 cfu/m^3; $F = 0.09$, $P > 0.05$). In all three points, however, a significant increase in the mean bacterial load was observed under operational conditions, immediately after placing the patient on the operating table (A1 = 79.2 ± 52.2 cfu/m^3, $F = 38.54$, $P < 0.001$; A2 = 61.2 ± 38.8 cfu/m^3, $F = 28.92$, $P < 0.001$; A3 = 69.1 ± 56.8 cfu/m^3, $F = 21.09$, $P < 0.001$; Figure 1).

In the 20 procedures in which the Bair Hugger was used, the mean bacterial load values were significantly increased in the three points compared with the at-rest conditions (A1 = 41.7 ± 28.1 cfu/m^3, $F = 15.6$, $P < 0.001$; A2 = 42.2 ± 28.6 cfu/m^3, $F = 12.2$, $P = 0.001$; A3 = 42.3 ± 28.2 cfu/m^3, $F = 12.62$, $P < 0.001$; Figure 1). However, in point A1 there was a significant reduction of the mean bacterial load values between the moment in which the patient was placed on the operating table and after the use of the Bair Hugger ($F = 8.62$, $P < 0.05$; Figure 2).

The mean bacterial load recorded during the 20 procedures in which the full body forced-air warming system was employed was 36.8 ± 24 cfu/m^3 around the right axilla, 42.7 ± 38.8 cfu/m^3 around the left axilla and 45.1 ± 39.8 around the forced-air blower.

Fungal contamination was uncommon; *C. parapsilosis* was found on the non-disinfected skin of one patient, and *Aspergillus flavus* was found in the air rising around the axilla of another subject.

All the subjects in this study had an uncomplicated postoperative course, free from surgical wound infection, and from systemic complications such as cystitis or bronchopneumonia.

Discussion

Lee *et al.* demonstrated that measurements from different active air samplers may not be directly comparable, despite a comparison of three sampling devices, collecting simultaneous samples, showing high linear correlations between methods.[24] The same evidence is underlined in the CDC guidelines for environmental infection control in healthcare facilities.[25] Perioperative

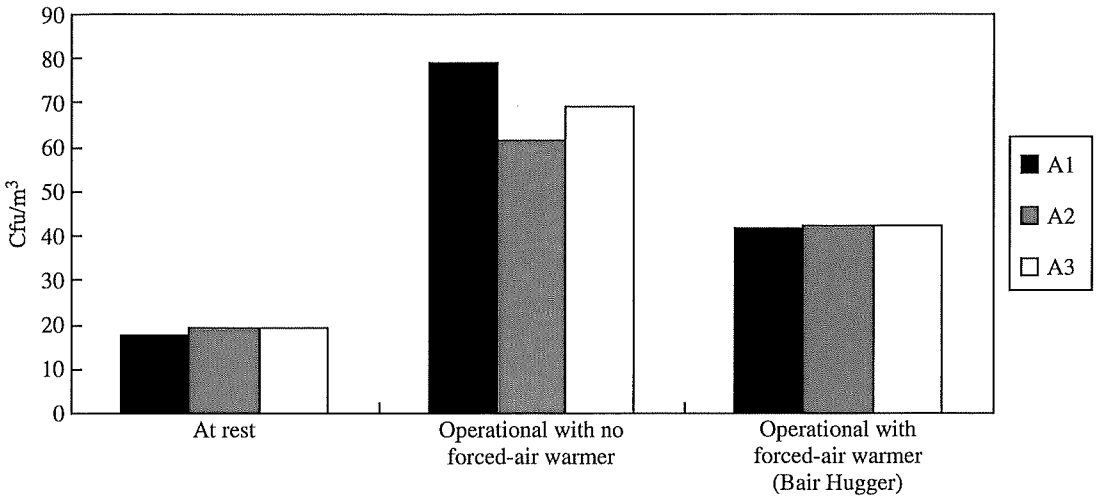

Figure 2 Mean bacterial load (cfu/m^3) in the three sampling points in at-rest and operational conditions and after placement of the forced-air blanket.

hypothermia is a common phenomenon, associated with physical factors such as exposure of patient to the operating theatre ventilation system and the infusion of cold solutions, but more importantly to anaesthesia-induced alterations on the individual's thermal homeostasis mechanisms.

Within the first hour of induction, both general and local anaesthetics act on the sympathetic system, inhibiting peripheral vasoconstriction and causing a redistribution of the heat from the body core to the periphery. In addition, the reflex shivering mechanism can be diminished, especially if there is associated administration of muscle relaxants.[26] The Bair Hugger blanket is considered to be among the most effective systems for achieving and maintaining a correct perioperative regulation of body heat.[27,17,28] It exploits the active warming principle, transferring the warmth of the inner circulating heated air to the patient's body surface, by convection.[9]

The Bair Hugger is not indicated in surgical situations that cannot offer a sufficient skin-blanket coverage area to maintain adequate body heat, including liver transplantation, major abdominal surgery, patients with multiple trauma, etc.[11,29] When it can be used, the system has the advantages of being non-invasive, cheap and simple to use, and above all effective. In our study, no patient developed any of the complications of hypothermia described in the literature, such as hypertension, myocardial ischemia, ventricular tachycardia, haemorrhage resulting from alterations of the platelet function and the activity of some enzymes involved in the clotting cascade, or local or general infections associated with cold-induced skin vasoconstriction.[1,2,30] The latter induces a reduced oxygen tension in subcutaneous tissues, rendering them more susceptible to microbial invasion and to neutrophil oxidation-induced inhibition of lymphocyte antibody formation and killing functions.[3]

The role of the forced-air body blanket as a potential source of infection is still controversial. Avidan *et al.* demonstrated a higher airborne bacterial load in the air samples analysed, and a higher incidence of nosocomial infections in patients kept warm using the Bair Hugger.[12] More recent studies, however, have not found a significant increase in the bacterial load in the operating theatre attributable to use of the system;[13] whereas other studies that did report such an increased bacterial load did not find an associated significant increase in the frequency of nosocomial infections.[31]

The results of this study seem to point to the same conclusion. In none of the surgical patients did a nosocomial infection develop. Although a significantly increased bacterial load was recorded both after the patient's entry into the operating theatre ($P < 0.001$) and after placement of the body-warming system at all the sampling points, not one patient in this study developed a nosocomial infection. There was also a statistically significant difference in airborne bacterial load during operations in which the blanket was or was not used. In any case, in two of the sampling points (A2 and A3) no significant differences ($P > 0.05$) were observed between the two increases, although the mean bacterial load was numerically lower (Figure 2) after application of the Bair Hugger than immediately after placement of the patient on the operating table. Indeed, at sampling point A1, the increase in the bacterial load seemed to be significantly lower ($P < 0.05$)

between the moment in which the patient was placed on the operating table and after use of the body-warming system.

In light of the results reported here, the Bair Hugger system does not seem to pose a real risk of nosocomial infections, while it does offer the advantage of preventing the potentially grave consequences induced by hypothermia during major orthopaedic surgical procedures. The increased bacterial load found after application of a body-warming system appears to be comparable to, or lower than, the load present at the time of placement of the patient on the operating table. This provides further confirmation of the literature data supporting the contention that the main potential contamination factor in the operating theatre is the presence of the theatre medical staff themselves, their movements, and in general their behaviour.

Our study has some limitations. The sample size of patients was small for the calculation of the statistical incidence of surgical site infection after the use of the Bair Hugger. Further studies are needed to determine the security of this active warming system. Besides, it is evident that the operating theatre personnel themselves play an active rule in introducing potential nosocomial pathogens into the environment. This variable is not easily quantifiable.

Conflict of interest statement
None declared.

Funding source
University of Bari.

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EXHIBIT 9

Bair Hugger Warmer Does Not Increase Microbial Contamination in the Operating Room.

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ABSTRACT

To determine if the Bair Hugger warming device increases contamination in the operating room we conducted microbial surveillance in twenty cases randomly assigned to receive patient warming with (BH) or without Bair Hugger (NBH). Microbial culture plates were exposed in the O.R. during cases and rates of contamination were determined by a microbiologist blinded to the group. There were no detectable differences in contamination rates between groups, (NBH mean = 7.33 colonies, sd = 1.64; BH mean = 7.27 sd = 1.55) and no post-operative wound infections. The Bair Hugger does not increase microbial contamination in the operating room.

INTRODUCTION

Maintenance of patient temperature during anesthesia and surgery is an important task for the anesthesiologist. The BAIR HUGGER forced-air warming system (Augustine Medical Inc., Eden Prairie, MN) consists of a filtering and heating unit with a flexible hose to inflate a disposable patient cover made of paper and plastic. Filtered and warmed air is directed over the patient via numerous small holes in the cover. Currently no data exists regarding the potential of the device to cause microbial contamination in the operating room or peri-operative infection in surgical patients. This study was designed to determine if the Bair Hugger system increases operating room contamination.

MATERIALS AND METHODS

Twenty adult ASA class I and II patients scheduled for oral or maxillofacial surgery were randomly assigned to two groups, Bair Hugger (BH) or non Bair Hugger (NBH), as the warming method for each case. We surveyed the same operating room, surgical, anesthesia and nursing staff. Normal access and activity in the O.R. was permitted during the study. Sets of plates comprising

two microbial culture media, Chocolate Agar (CAP) for bacteria and Sabaraud Agar (SAB) for fungi were placed at each of six specific locations around the operating room (diagram 1). An initial case was studied without use of the Bair Hugger to determine the relationship between contamination of the plates (expressed as number of colonies per plate) and duration of exposure. Six sets of two plates were placed in each of the six locations just before the start of surgery and sets of two were removed from each location every twenty minutes.

In later cases one set of plates was exposed in each location for the duration of the case or a maximum of two hours. After incubation the number of colonies per plate were counted and identified by genus by one qualified microbiologist who was blinded to location, warming method and duration of exposure. Data were evaluated using analysis of covariance and repeated measures of covariance treating the six locations as six levels of the repeated factor. The covariate was always duration.

RESULTS

In the first case bacterial colony count and duration of exposure were linearly related; the rate of contamination was constant (figure 1). In the other cases with exposure times ranging from 30 to 120 minutes we were unable to identify any differences in contamination rates between groups (table 1). Some locations showed consistently higher levels of contamination than others however the differences were not influenced by the use of the Bair Hugger. All patients were reviewed at routine follow-up. No patient in either group developed a post operative wound infection.

DISCUSSION

The Bair Hugger maintains a temperature controlled micro-environment for the patient. In addition to minimizing radiant and convective heat loss it also provides patient warming. Potential benefits include faster recovery from anesthesia; lower incidence of complications such as shivering, problems with blood pressure, increased oxygen requirement and disordered blood coagulation; and increased comfort (1,2). The device may cause alteration of air movements within the O.R. and it is unknown if this results in increased contamination of the surgical field or operating instruments. Our microbial surveillance of twenty cases was intended to detect gross changes in contamination.

The Bair Hugger did not increase contamination of the operating room in our study. This may be due to several factors. All air passing through the Bair Hugger heating unit passes through a 0.2μm filter on the inlet. Also, the patient cover can be sealed at one end by adhesive strip to prevent flow of air directly into the surgical field. Further, output of warmed air is 35L/min or 2100L/hr, representing only a small fraction of the normal operating room ventilation of about 10 room changes per hour, or about 750,000L/hr. Finally, the velocity of the moving air and thus its potential for causing turbulence is low as the 35L/min is directed over the patient via small holes in the patient cover.

The benefit of the O.R. model Bair Hugger is maintenance of patient temperature intra-operatively. The risks of this method of thermal maintenance are not completely known but this study of bacterial contamination in six locations in the operating room reveals that the Bair Hugger does not increase the rate of contamination. We conclude that its use does not increase the risk of surgical wound infection.

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DIAGRAM 1

Plan of O.R.

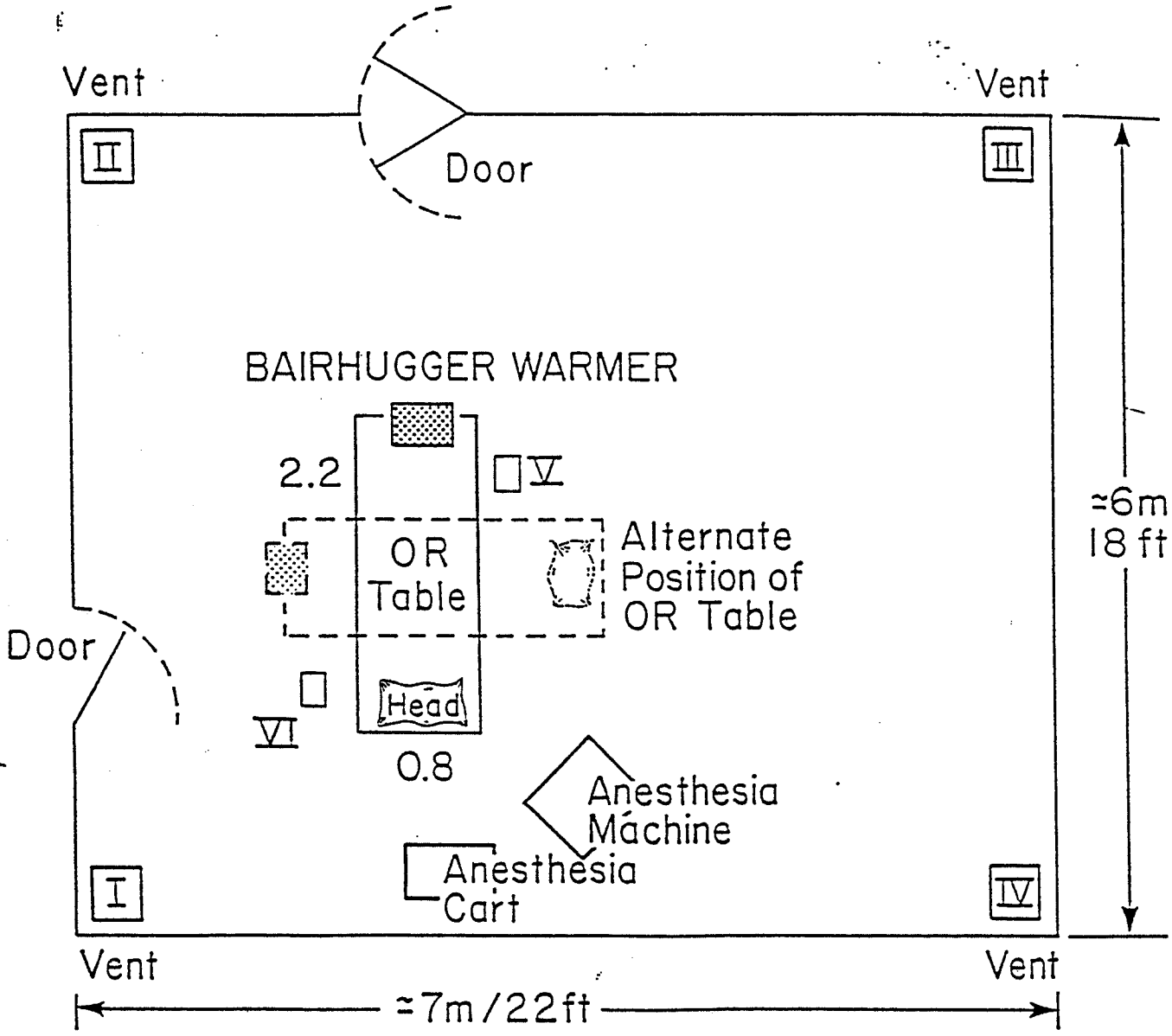

FIGURE 1

$r^2=0.8732$

x (min)	0	20	40	60	80	100	120
y (count)	0	16.8	19.0	22.0	26.4	30.3	32.5

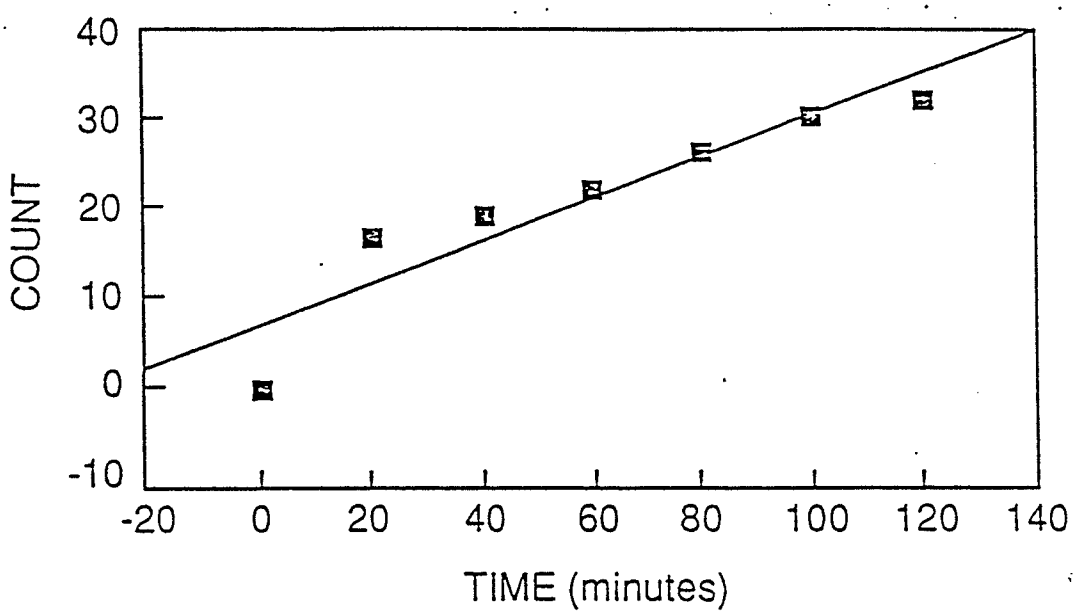

TABLE 1

Location	NBH mean	SD	BH mean	SD	P value
I	3.19	1.0	3.37	0.91	0.9345
II	2.37	0.67	2.65	0.71	0.5296
III	3.00	0.72	3.03	0.79	0.9299
IV	1.97	0.75	2.62	0.75	0.1068
V	3.88	1.60	2.95	1.10	0.0501
VI	3.06	1.05	3.21	0.86	0.7278
ALL	7.33	1.64	7.27	1.56	0.7067
Corner	5.30	1.21	5.79	1.38	0.5878
Table	5.01	1.55	4.39	1.03	0.2138
Door	4.36	1.06	4.51	1.07	0.9984
Vent	3.04	0.87	3.69	0.94	0.1976
Time	81	41	96.5	36.5	

EXHIBIT 10

ABSTRACTS

Anesthesiology
V 81, No 3A, Sep 1994

A562

TITLE: CONVECTION WARMING IN THE OPERATING ROOM: EVALUATION OF BACTERIAL SPREAD WITH THREE FILTRATION LEVELS

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With the recent increase in use of convective heating for warming patients in the operating room, there has been concern regarding possible increases in surgical infections. Several manufacturers have produced convective warming machines with varying degrees of filtration. One previous paper studied a 0.2 micron filter and 95% efficient machine and blanket and found no increase in bacterial spread (1). Our study was designed to test three different units with three levels of filtration and to test the filtration alone.

The units tested were a WarmAir Model 130 with 5 micron filtration, a BairHugger 550 with 0.2 micron filter and 95% efficiency rating, and a WarmAir Model 133 with a 0.02 micron filter with 99% efficiency. The machines were placed in a standard, fully equipped operating room at the head of the OR table. A plate of cultured beta hemolytic strep was placed 10 inches from the filter inlet. A fresh agar plate was then placed 12 inches from the outlet of the convective unit. The machine was then turned on. Group 1: WarmAir Model 130 - high temperature. Group 2: WarmAir Model 130 - ambient temperature. Group 3: BairHugger - ambient temperature. Group 4: WarmAir Model 133 - ambient temperature. The machines were kept on for two hours for each sampling time. A total of ten samples for each group were obtained.

Group 1 had one plate that grew one colony of a probable staphylococcus species. Group 2 had one plate that had six colonies of coagulase negative staphylococcus and one plate that had two colonies of coagulase negative staphylococcus. Groups 3 and 4 were all no growth. There was no transmission of beta hemolytic streptococcus by the convective warming units in any of the groups.

The convective warming units, as tested, are effective in preventing the transmission of large loads of bacteria through the filtration system. In no case with these machines was a marker bacteria of beta hemolytic streptococcus transmitted through the system. This includes a machine with only a 5 micron filter. Although the filtration systems tested all appeared to be effective, this study did not look at further contamination which may be possible due to the increased movement of air over unsterile fields. However, this study does show that convective warming with a filter rated up to 5 microns in size is effective in preventing the transmission of bacteria through the system.

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EXHIBIT 11

Anaesthesia, 1997, **52**, pages 1073–1076

APPARATUS

Convection warmers – not just hot air

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Summary

We sought to determine whether the forced air convection warmers (nine Bair Huggers, Augustine Medical, and one Warm Touch, Mallinkrodt Medical) used in our operating theatres could be a source of microbial pathogens. Agar plates were placed directly in the air stream of the warmers. Four of these grew potentially pathogenic organisms. When the warmers were set to blow through perforated blankets, no growth occurred. Three of the warmers were swabbed and sites of colonisation were found in their hoses. After fixing a microbial filter to the end of the hose, organisms were no longer detectable. We conclude that these warming devices are a potential source of nosocomial infection. They should only be used in conjunction with perforated blankets, should have their microbial filters changed regularly and their hoses sterilised. The inclusion of a microbial filter into the nozzle of the hose could be incorporated into the design of the warmer.

Keywords *Equipment*; temperature blankets. *Infection. Hypothermia.*

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Accepted: 3 May 1997

Forced air convection warming devices have revolutionised our management of hypothermia, especially in the operating theatre. They have proved to be very efficient in providing thermal homeostasis during surgery [1, 2]. The maintenance of normothermia has been associated with a reduction in the incidence of postoperative surgical wound infection [3]. Peri-operative hypothermia is also associated with several other complications, including shivering, decreased drug metabolism and clearance, and impaired wound healing [4]. Thus far, studies suggest that convection warming does not increase microbial contamination in the operating room [5, 6].

Convection warmers entrain environmental air through a microbial filter (0.2 μm pore size). The air is heated and blown through a detachable hose. The manufacturers of convection warmers recommend that these devices be used only in conjunction with a specialised blanket with perforations on its underside. They suggest that the filter be changed every 6 months or after 600 h of usage.

In practice, these devices are frequently used without specialised blankets with warm air blowing directly onto the patient. Filters are often not replaced, according to the manufacturer's recommendations (Augustine Medical).

We set out to determine whether these devices blow contaminated air. Thereafter, we sought to ascertain whether the use of perforated blankets could prevent the detection of such contamination. We further tried to locate possible sites of contamination. Finally, we sought to establish whether placing a microbial filter on the end of the hose of the warming devices might filter out organisms.

Methods

A vascular operating theatre, which is cleaned daily with Bacterex-C® (disinfectant cleaner containing organic chloride and detergent compounds), was chosen as the site of the experiments. Operating theatre temperature ranged between 21 and 23 °C and humidity between 61 and 67%. The investigators wore full operating theatre clothes and sterile gloves and remained at a distance of at least 1 m from the equipment for the duration of the experiments. Agar plates were on sterile towels on the operating table.

Experiment 1: are microbes present in the air stream of warmers?

Ten intra-operative patient warming devices (nine Bair Huggers, Augustine Medical, and one Warm Touch, Mallinckrodt Medical) were assessed. Each warmer was placed sequentially on a standard place on the floor. The nozzle of the hose was suspended from an infusion stand 40 cm above two agar plates. The machine was turned on to blow air at 43 °C over the plates for 5 min. There was a break of 5 min between each machine. Control plates were placed at the beginning and end of the experiment with no warmer blowing.

Experiment 2: do perforated blankets reduce microbial contamination?

Two of the warmers which had yielded early growth on agar plates were assessed further. The warmers were attached to infusion stands. Perforated blankets were elevated over agar plates. The warmers were set to blow air at 43 °C through the blankets over the plates for 30 min. Control plates were placed under a blanket for 30 min without air blowing. Warmed air was also blown directly onto agar plates as had been done in Experiment 1.

Experiment 3: can colonisation be localised?

Three of the warmers whose agar plates had grown organisms were swabbed from both sides of the internal microbial filter and from the inside of the hose at its proximal (warmer) and distal (patient) ends.

Experiment 4: can contamination of the air stream be reduced?

The same three warmers were set to blow onto agar plates for 5 min with and without microbial filters fitted to the distal ends (nozzles) of their hoses. The filters used were DAR Hygrobac Filters for breathing systems (DAR S.p.A). These serve as both bacterial and viral filters.

Microbiology methods

Two agar plates were used to sample warmed air from each machine. One contained dextrose agar with chloromycetin (DAC) and the other 5% horse blood agar. Following completion of each experiment, each plate was wrapped in laboratory film. Swabs and plates were transported to the laboratory immediately, where swabs were plated onto DAC and 5% horse blood agar. The plates were incubated at 37 °C and inspected every 2 days for growth. Blood plates were kept for a total of 7 days and DAC plates for 1 month before being called negative. Visible colonies growing on the plates were picked off and identified according to standard bacteriological and fungal laboratory procedures.

Results

Experiment 1: microbes are present in the air streams of warmers (Table 1)

There was a pure growth of *Aspergillus fumigatus* on both control plates. Organisms grew on plates from four of the 10 (40%) warmers. The organisms cultured were *Staphylococcus xylosus* (from two plates), *S. epidermidis* (from one plate), *Corynebacterium* spp. (from one plate) and *Cryptococcus albidus* (from one plate). *A. fumigatus* was also isolated from two of the test plates.

Experiment 2: perforated blankets reduce microbial contamination (Table 2)

The control plates grew no organisms. The agar plates directly in the stream of the warmers both grew

Table 1 Microbes present in the air streams of warmers.

Machine type	Number	Hours in use	Usual theatre	Organisms cultured
Bair Hugger 500E	1		general surgery	none
Bair Hugger 500E	2		neurosurgery	none
Bair Hugger 505	3	245.6	cardiac surgery	*Corynebacterium* spp.
Bair Hugger 505	4	426.2	paediatric surgery	none
Bair Hugger 505	5	111.1	paediatric surgery	*Staphylococcus xylosus, Aspergillus fumigatus*
Bair Hugger 505	6	157.7	recovery room	none
Bair Hugger 505	7	112.9	paediatric surgery	none
Bair Hugger 505	8	666.2	general surgery	*Cryptococcus albidus, A. fumigatus, S. xylosus*
Bair Hugger 505	9	718.5	general surgery	none
Warm Touch 500	10		cardiac surgery	*S. epidermidis*
Control 1				*A. fumigatus*
Control 2				*A. fumigatus*

Table 2 Microbial contamination with and without the use of perforated blankets.

Machine number	Method used	Organisms cultured
5	Under blanket for 30 min	none
5	In direct air stream for 5 min	*S. epidermidis* and *Corynebacterium* spp.
8	Under blanket for 30 min	none
8	In direct air stream for 5 min	*S. epidermidis*
Control	Under blanket for 30 min without warm air blowing through	none

Table 3 Sites of colonisation in three warmers.

Machine number	Site of swab	Organisms cultured
3	inside of filter	none
3	outside of filter	*Staphylococcus aureus*
3	proximal hose	*Corynebacterium* spp.
3	distal hose	*S. epidermidis*, *Corynebacterium* spp.
5	inside of filter	none
5	outside of filter	*S. epidermidis*, *Aspergillus niger*, *A. fumigatus*
5	proximal hose	*Bacillus* spp.
5	distal hose	none
8	inside of filter	none
8	outside of filter	*S. epidermidis*, *Bacillus* spp., *A. niger*
8	proximal hose	*Corynebacterium* spp., *A. fumigatus*
8	distal hose	*A. fumigatus*

organisms (*S. epidermidis* in two and one additionally grew a *Corynebacterium* spp.). Those which had warm air blown on them through the perforated blankets grew no organisms.

Experiment 3: microbial colonization of warmers is detected (Table 3)

Swabs from the outer surfaces of the filters from three warmers grew *Staphylococcus aureus, S. epidermidis, A. fumigatus, Aspergillus niger* and *Bacillus* spp. None of the swabs from the inner surfaces grew organisms. The proximal hose swabs grew *Corynebacterium* spp., *Bacillus* spp. and *A. fumigatus.* The distal hose swabs grew *S. epidermidis, Corynebacterium* spp. and *A. fumigatus.*

Table 4 Contamination with and without a microbial filter attached to the nozzle of the hose of the warmer.

Machine number	Method used	Organisms cultured
3	blowing through filter	none
3	direct blowing	*Acinetobacter lwoffii*
5	blowing through filter	none
5	direct blowing	*Staphylococcus epidermidis*
8	blowing through filter	none
8	direct blowing	*S. epidermidis*

Experiment 4: a microbial filter attached to the nozzle of the hose reduces contamination (Table 4)

Plates placed directly in the air streams of the three warmers grew *Acinetobacter lwoffii* and *S. epidermidis.* When microbial filters were fitted to the nozzles of the same warmers, there was no growth.

Discussion

Infection control is of paramount importance to all practitioners, particularly at a time when multidrug resistant organisms are emerging. We have detected a potential source of nosocomial infection at our hospital. The filters in convection warmers (when replaced regularly) should protect against entrained bacterial and fungal pathogens, but may not prevent colonisation in the machines distal to the filters.

Our results indicate that, when air was sampled directly from the warming devices (without the use of the recommended perforated blankets), microbial pathogens were detectable in almost half of the devices tested. When the experiment was repeated with the use of the recommended blankets, contamination of sampled air (through the blankets) was no longer detected.

Organisms cultured in the experiments are typical of skin flora (*S. epidermidis, S. xylosus, A. lwoffii* and *Corynebacterium* spp.) or are ubiquitous organisms present in the

environment (*A. fumigatus*, *A. niger*, *Bacillus* spp. and *C. albidus*). These organisms are potentially pathogenic, especially in immunocompromised patients and when prosthetic devices are present (e.g. indwelling central lines, heart valves).

Following this study, we have altered policy in our hospital. We now ensure that forced air convection warmers are only used when attached to perforated blankets. We also recommend that microbial filters be changed as specified by the manufacturer and that detachable hoses are sterilised regularly. A microbial filter fitted to the nozzle of the hose could be incorporated into the design of the warmer to reduce the risk of contamination.

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EXHIBIT 12

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Original contribution

Airborne bacterial contamination during orthopedic surgery: A randomized controlled pilot trial

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ABSTRACT

Study objective: Several factors such as lack of unidirectional, turbulent free laminar airflow, duration of surgery, patient warming system, or the number of health professionals in the OR have been shown or suspected to increase the number of airborne bacteria. The objective of this study was to perform a multivariate analysis of bacterial counts in the OR in patients during minor orthopedic surgery.
Design: Prospective, randomized pilot study.
Setting: Medical University of Vienna, Austria.
Patients: Eighty patients undergoing minor orthopedic surgery were included in the study.
Interventions: Surgery took place in ORs with and without a unidirectional turbulent free laminar airflow system, patients were randomized to warming with a forced air or an electric warming system.
Measurement: The number of airborne bacteria was measured using sedimentation agar plates and nitrocellulose membranes at 6 standardized locations in the OR.
Main results: The results of the multivariate analysis showed, that the absence of unidirectional turbulent free laminar airflow and longer duration of surgery increased bacterial counts significantly. The type of patient warming system and the number of health professionals had no significant influence on bacterial counts on any sampling site.
Conclusion: ORs with unidirectional turbulent free laminar airflow, and a reduction of surgery time decreased the number of viable airborne bacteria. These factors may be particularly important in critical patients with a high risk for the development of surgical site infections.

1. Introduction

Surgical site infections (SSIs) are among the most severe complications in orthopedic and trauma surgery and have a serious impact on patient morbidity and mortality. Despite strict perioperative hygiene standards the incidence of postoperative orthopedic wound infections is still high ranging between 0.1% to 12% [1–3].

The infected surgical wound is usually colonized by commensal bacteria originating from the patient's own skin (endogenous) or exogenously by bacteria airborne in the operating room (OR). While there is general agreement on the protective effect of adequate skin antisepsis on the rate of SSIs, strategies to reduce airborne contamination are still disputed. One possibility for reducing airborne contamination is the use of a unidirectional turbulent free laminar airflow ventilation system (laminar airflow). Surprisingly, while the benefit of laminar airflow systems seems intuitive, evidence to implement laminar airflow as a standard requirement for every OR is contradictory [4,5]. As laminar airflow is costly and conclusive evidence is lacking, many hospital administrators hesitate to implement laminar airflow technologies in their ORs. In the US only 30% of 256 hospitals in 4 US states reported the regular use of laminar airflow in 2005 [6].

However, also other factors such as duration of surgery, number of OR staff [7] and use of forced air patient warming [8] might influence airborne bacterial displacement and could blur eventual beneficial effects of laminar airflow.

The aim of the study was thus to determine the influence of four intraoperative factors – use of laminar airflow, duration of surgery, number of health professionals present and use of forced air - on airborne bacterial contamination, measured by 6 sedimentation plates at standardized locations in the OR including two locations on the instrument table.

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0952-8180/

Abbreviations

OR	Operating room
SSI	Surgical site infection
Laminar airflow	Laminar airflow ventilating system
CFU	Colony forming unit

2. Materials and methods

The study was approved by the Ethics Committee of the Medical University of Vienna and patients' written, informed consent was obtained in all patients undergoing minor orthopedic interventions either the day before surgery or on the day of surgery, if the patient had not been admitted to the hospital on the day before surgery, from January 2009 to June 2009. A manuscript using the same study patients' data as this paper demonstrated that different laminar airflow sizes affected the bacterial count on the instrument table [9]. In the present study bacterial counts on *all* positions were analyzed with multivariate methods, including the factor "patient warming system". Patients were randomized with excel random numbers to intraoperative warming with either a BairHugger forced air upper-body warming blanket (Arizant, Eden Prairie, MN) or a HotDog upper-body electric blanket (Augustine Biomedical + Design, Eden Prairie, MN) after induction of anesthesia. Randomization was performed by a medical student not involved with the study proceedings and delivered via opaque envelopes. Patients had to meet the following inclusion criteria: Age between 18 and 90 years, a BMI of 20–30, surgery lasting at least 1 h (expected).

A single observer (R.O.) present during each intervention monitored the following parameters: Number of health professionals present in the OR (maximum), duration of surgery (from skin incision to last suture), presence of a laminar airflow, and method of patient warming (forced air versus electric polymer blanket).

2.1. Measurements

Number of airborne bacteria was assessed by positioning four agar plates (90 mm diameter) in the OR and two nitrocellulose membranes (47 mm diameter) directly on the sterile instrument table. The first agar plate (plate 1) was positioned 15 cm above floor level, the second (plate 2) at table level, the third (plate 3) at 150 cm (plates 1–3 behind the surgical draping at the side of the anesthesiologist), and the fourth (plate 4) at table level with a distance of approximately 50 cm to the sterile operating field (on the surgical side of the draping). The nitrocellulose membranes (plates 5, 6) were both placed at the instrument table adjacent to each other (Fig. 2).

The agar plates and the nitrocellulose membranes were collected at the end of the surgical intervention. The nitrocellulose membranes were transferred to agar plates. All plates were then incubated for 48 h at 36°. After incubation the colony forming units (CFUs) were counted. The results were analyzed in CFU/m^2/h to adjust for OR size.

3. Statistical analysis

All values are displayed as means ± standard deviation, median (25th–75th quartile) or frequency (%), as appropriate. Plates 5 and 6 were averaged before analysis. Sample size was estimated with bacterial growth on the instrument table plates (mean of plates 5 & 6) as primary outcome. With an alpha error of 0.05, a power of 0.8 and an effect size of 0.7 for difference of airborne contamination by non-forced air warming versus forced air warming, 40 patients per group were calculated for a Wilcoxon-Mann-Whitney test as primary analysis. This simplified model was used to calculate the sample size estimate, since not enough previous knowledge about the possible relation of the main parameter of interest and airborne bacterial contamination was available.

Due to the skewed nature of bacterial growth data a generalized linear model with gamma distribution and log-link was used to analyze influence of time, number of health professionals, presence of laminar airflow and type of patient warming system on the number of viable bacteria at the different locations as secondary analysis. A QQ-Plot was performed to assess adequacy of assumption of distribution, which proved to be applicable.

G*Power (Duesseldorf, Germany) was used for sample size estimation; SPSS 23.0 (IBM, Armonk, NY, USA) was used for statistical analysis. A $p < 0.05$ was considered statistically significant.

4. Results

All patients completed the study. The average age of patients was 43 ± 15 years, with a weight of 78 ± 15 kg and a height of 174 ± 9 cm. 44 male (55%) and 36 female (45%) patients were included (see Fig. 1). Details about surgical interventions, number of health professionals present, duration of surgery, the use of forced air or electric blanket warming and laminar airflow are displayed in Table 1.

There was no difference for bacterial growth on the mean of plates 5 & 6 between the forced air and the non-forced air warming group ($p = 0.6$, Wilcoxon-Mann-Whitney test). Results of the multivariate model indicate, that a longer duration of surgery increased bacterial count on plates 1 to 4 and absence of laminar airflow increased bacterial count on plates 1 to 6 significantly (Table 2). There was a trend, that longer duration of surgery increased bacterial count on plates 5 & 6 ($p = 0.07$) as well. There was no difference for forced air versus resistive warming for bacterial count on either plate. A reduced model without patient warming method did not change any significances discovered in the extended model.

In a follow-up of all patients until hospital discharge (range 0–4 days), no SSIs were reported.

5. Discussion

In the present study we found, that the absence of laminar airflow and a longer duration of surgery increased airborne bacteria in the OR. In patients with a high risk for surgical wound infections, optimization of these factors may be an important preventive measure.

Despite being widely used the benefits of laminar airflow environments in ORs are still disputed. While the concept of clean, laminar flowing air to avoid SSIs is plausible and supported by some studies, other authors disagree as they were not able to demonstrate any beneficial effect of laminar airflow systems [4–6,10,11]. According to the present study other factors may be just as important as the availability of a laminar airflow system, e.g. a longer duration of surgery might completely annihilate the contamination-reducing effects of laminar airflow.

Particularly number of health professionals in the OR may be an important factor to consider when reducing airborne contamination, [7] however this effect could not be reproduced in our study, possibly due to the limited number of patients.

As mentioned the duration of surgery is in our study a very influential factor determining the amount of bacterial sedimentation. However, this factor itself obviously is dependent again on a number of other factors, which may not all be equally optimizable: the skill of the surgeon, type of surgery, OR management, patient's surgical site and others [12, 13].

An important finding of our study was that the type of patient warming did not influence the amount of bacterial sedimentation on either plate position. It is important to remember, that the introduction of an efficient forced-air patient warming system initially led to a major decrease in wound infections, which had a higher incidence in un-

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CONSORT 2010 Flow Diagram

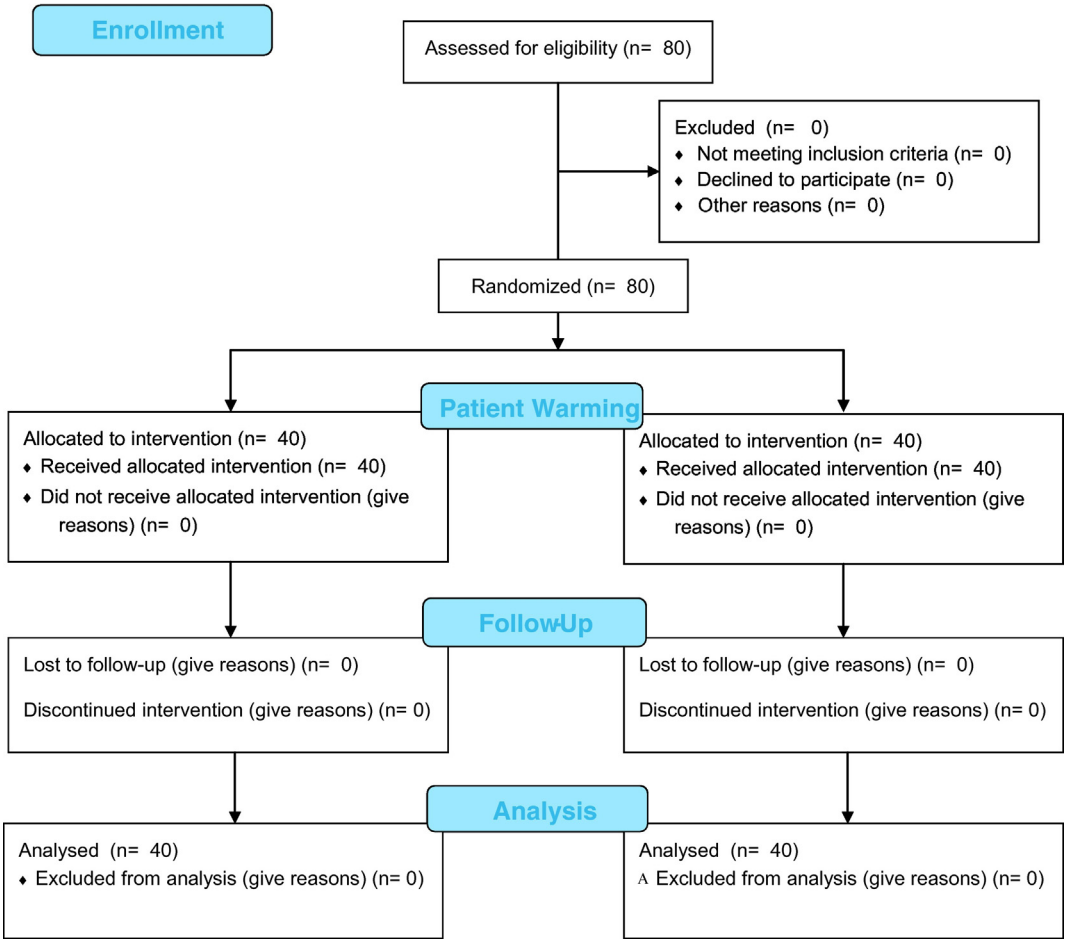

Fig. 1. Consort flow diagram.

warmed patients with accidental perioperative hypothermia [14]. Evidence for the many beneficial effects of perioperative normothermia is undeniably fully established. However, over the last years there has been a lively discussion if the air from forced air warming devices might directly distribute bacteria originating from the environment or the inside of the device into the sterile field in clinically relevant amounts, as micro-organisms have been detected in such warming devices and in the air coming from those devices [15–18].

Table 1
Demographic data, type of surgery, number of health professionals, duration of surgery by patient warming method and use of laminar airflow.

	Forced air (n = 40)		Electric blanket (n = 40)	
	Laminar flow (n = 20)	No laminar flow (n = 20)	Laminar flow (n = 20)	No laminar flow (n = 20)
Age of patients (years)	42 ± 20	48 ± 12	36 ± 8	45 ± 15
Gender of patient (male/female)	10/10	12/8	14/6	7/13
Surgery (%, mean duration in min ± SD; p = 0.13, chi square test)				
Athroscopy of knee, shoulder and wrist joint (51.48 ± 11.0 min)	55%	35%	70%	55%
Osteosynthesis (47.08 ± 11.96 min)	25%	20%	15%	5%
Metal implant removal (47.50 ± 15.00 min)	0%	20%	5%	5%
Surgery of ligaments and of soft tissue (45.00 ± 13.28 min)	15%	25%	10%	35%
Total knee replacement (60 min)	5%	0%	0%	0%
Number of health professionals	9 (7–12)	7 (5–9)	9 (6–12)	7 (5–9)
Duration of surgery (min)	57 ± 7	40 ± 10	56 ± 7	43 ± 12

Duration of surgery: mean ± SD, number of health professionals: median [range], surgery: frequency (% of all interventions, n = 80).

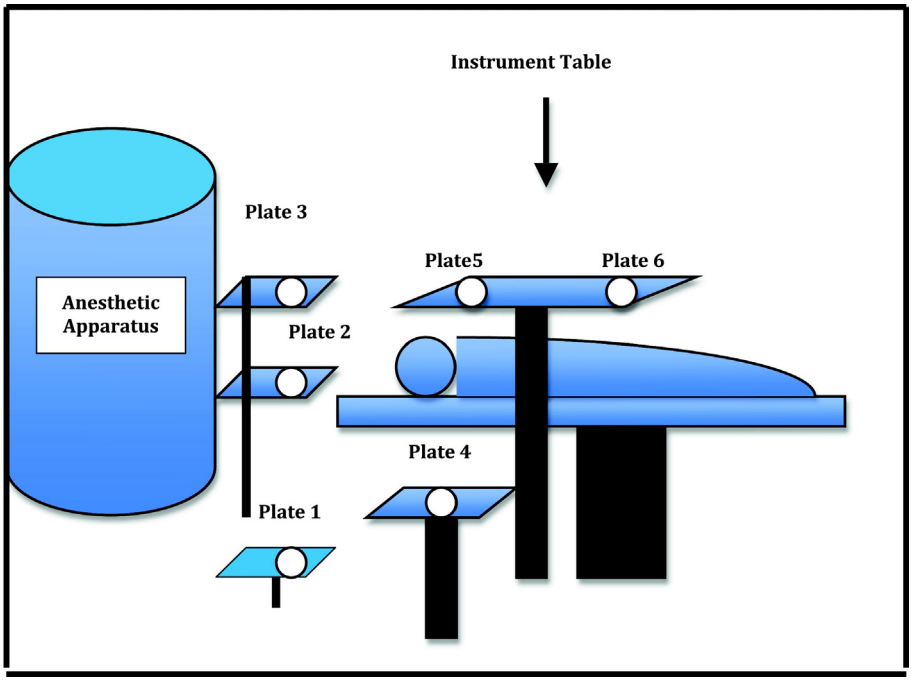

Fig. 2. Positioning of agar plates during the study – plate 1 was positioned 15 cm above floor level, plate 2 at table level, plate 3 at 150 cm, plate 4 at table level with a distance of approximately 50 cm to the sterile operating field. The nitrocellulose membranes (plates 5, 6) were both placed at the sterile instrument table adjacent to each other.

Another focus of this discussion was on the disruption of laminar airflow by forced air blowers, which was confirmed by some studies [19–22] and rebutted by others [23–26].

In our study it was not possible to detect any higher bacterial counts on any plate in the forced air warming group versus the resistive warming group. The study may obviously not be generalized for an overall safety statement on forced air warming, and is primarily applicable in the particular surgical setup. However – with class action lawsuits "judging" the scientific question of forced air safety with unsuitable, i.e. legal, means subsequent studies are all the more warranted. Only a large, randomized, controlled trial of forced air warming versus non-forced air warming will help to decide, if patient outcome is influenced by the use of forced-air devices. Until this study has been performed, the hypothesized risks of forced air warming remain unclear. With a multitude of factors influencing a patient's risk for perioperative infection, only this kind of study will be able to answer the question, if forced air warming is a major influence on surgical wound contamination, whose voice can be reliably detected in the large choir of all the other factors, such as transmission via the anesthesiologist's [27] or surgeons hand, [28] skin preparation, sterile surgical technique, duration of surgery, surgical skill, patient-related risk factors such as obesity, diabetes mellitus or pre-existing colonization and inadequate antibiotic treatment [29] among many others.

The present study has several limitations. Surgery was primarily minor orthopedic surgery. Unsurprisingly, in the present study no SSIs occurred. However, a study with SSI as endpoint would have required a much larger setup, since SSIs are rare in the study's particular patient population. The upper-body position of the forced-air warming system in relation to the sterile field on the lower body may have reduced the effect of forced air warming turbulence on airborne contamination in the sterile field. Only the maximum number of health professionals present was recorded in the present study. A more elaborate approach has recently been presented by Masursky et al. [30] However, since the surgeries were not very complex and their duration was relatively short, changes of number of health professionals during surgery was a rare occurrence. Furthermore, the factor "laminar flow" could not be randomized, since OR assignment could not be changed for study purposes. Finally, incidences of opening and closing of doors were not recorded – as the operating theatres are protected by an airlock system, the impact of this factor may not be a major influence.

In conclusion, the present study shows that in the setting of minor orthopedic surgery an OR with laminar airflow, a reduction of surgery time, by trend a reduced number of personnel present, but not the choice of a non-forced air patient warming system was associated with a decreased airborne sedimentation. Optimizing these factors in critical patients with a high risk for the development of SSI may allow further reduction in the incidence of SSIs. As far as forced air warming is concerned subsequent large, randomized controlled patient studies are highly commended to allow evidence based conclusions regarding any influence of forced air warming on perioperative outcome.

Table 2
Results of a multivariate analysis of factors influencing bacterial deposition (generalized linear model with gamma distribution and log link, exp (B) and 95% Wald confidence intervals in brackets).

	Plate 1	Plate 2	Plate 3	Plate 4	Plate 5 & 6
Absence of laminar flow	2.42 (1.00–5.83)*	3.70 (2.05–6.67)#	3.48 (1.61–7.51)*	5.10 (2.59–10.06)#	2.18 (1.13–4.20)*
Presence of forced air warming	1.13 (0.74–1.71)	1.07 (0.70–1.65)	1.30 (0.7–2.38)	1.55 (0.92–2.60)	1.00 (0.56–1.80)
Duration (min)	1.05 (1.02–1.07)#	1.03 (1.01–1.05)*	1.05 (1.02–1.07)#	1.05 (1.03–1.07)#	1.02 (1.00–1.05)+
Number of health professionals in OR (5–12)	0.92 (0.72–1.17)	1.05 (0.93–1.20)	1.04 (0.80–1.35)	1.11 (0,90–1.37)	0.86 (0.66–1.11)

+ $p = 0.07$.
* $p \leq 0.05$.
# $p < 0.001$.

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All funding was provided by the Medical University of Vienna.

Conflict of interest

Oliver Kimberger has received financial support for studies and travel costs and fees for speaker assignments from the following companies producing patient temperature management products: Biegler GmbH, Mauerbach, Austria; Augustine Biomedical, Eden Prairie, MN, USA; Möck&Möck, Hamburg, Germany; Zoll, USA; Zoll, San Jose, CA, USA; 3 M, St. Paul, MN, USA; Dräger AG, Lübeck, Germany; 3M, St. Paul, MN, USA; The 37 Company, Amersfoort, the Netherlands.

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EXHIBIT 13

An APIC Guide

2010

Guide to the Elimination of Orthopedic Surgical Site Infections

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APIC's mission is to improve health and patient safety by reducing risks of infection and other adverse outcomes. The Association's more than 13,000 members have primary responsibility for infection prevention, control, and hospital epidemiology in healthcare settings around the globe. APIC's members are nurses, epidemiologists, physicians, microbiologists, clinical pathologists, laboratory technologists, and public health professionals. APIC advances its mission through education, research, consultation, collaboration, public policy, practice guidance, and credentialing

The Association of periOperative Registered Nurses (AORN) is the national association committed to improving patient safety in the surgical setting. AORN's mission is to promote safety and optimal outcomes for patients undergoing operative and other invasive procedures by providing practice support and professional development opportunities to perioperative nurses. AORN is the premier resource for perioperative nurses, advancing the profession and the professional with valuable guidance as well as networking and resource-sharing opportunities. AORN is recognized as an authority for safe operating room practices and a definitive source for information and guiding principles that support day-to-day perioperative nursing practice.

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- MRSA in Hospital Settings, 1st edition
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On the Cover:
Cover image courtesy of CDC/ Jeff Hageman, M.H.S.
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This 2005 scanning electron micrograph (SEM) depicted numerous clumps of methicillin-resistant *Staphylococcus aureus* bacteria, commonly referred to by the acronym, MRSA; Magnified 2381x.

Recently recognized outbreaks, or clusters of MRSA in community settings have been associated with strains that have some unique microbiologic and genetic properties, compared with the traditional hospital-based MRSA strains, which suggests some biologic properties, e.g., virulence factors like toxins, may allow the community strains to spread more easily, or cause more skin disease. A common strain named USA300-0114 has caused many such outbreaks in the United States. See PHIL 7823 for a black and white version of this micrograph.

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Guide Overview

The purpose of this guide is to provide practical tools, strategies and resources for infection preventionists (IPs), care providers, surgical staff and quality improvement teams to use in their efforts to eliminate surgical site infections (SSIs) in orthopedic surgery.

Scope

This guide focuses on orthopedic surgeries in clean, primarily elective cases, with a major emphasis on joint replacements. However, the tools, protocols and general information are also applicable to a variety of other orthopedic surgeries in both inpatient and outpatient settings. Because orthopedic surgery is performed in a variety of inpatient and outpatient settings, the need for increased vigilance, strict adherence to aseptic technique, attention to adequacy of reprocessing, and management of intraoperative breaches of sterile technique are vitally important to ensure a safe and consistent standard of care. Breaches of sterile technique, inadequate sterilization of equipment and lack of adherence to aseptic technique have been associated with outbreaks of SSIs.[1]

Several references and regulatory issues discussed in this guide pertain to the United States. However, many of the principles and practices are applicable to the global setting. Discussion of products outside the U.S. should comply with that jurisdiction's relevant licensing and regulatory authority requirements, which may be different from those of the U.S. Food and Drug Administration (FDA).

Key Concepts

An effective facility-wide infection prevention and control program is composed of many components and interventions that can reduce the risk of infection in surgery patients. This includes an understanding of the surgical population and the associated risk factors, effective methods for case finding, expertise in the analysis of data, effective communication of outcomes, and implementation of evidenced-based strategies to improve outcomes. Central to this theme is collaboration. In order to ensure patient safety and optimum patient outcomes, IPs, surgeons, perioperative staff, nurses, and all members of the healthcare team must work together to implement evidence-based practices that minimize the risk of infection.

Background

Klevens and others reported that in 2002, approximately 20% of total healthcare-associated infections (HAIs) were SSIs, making this the second most common HAI in U.S. hospitals. This report also estimates that 8,205 deaths occur from SSIs annually.[2] The Agency for Healthcare Research and Quality (AHRQ) reported that more than one million knee and hip arthroplasty surgeries were performed in hospitals in the United States in 2008.[3] This number, along with other orthopedic procedures, represents a significant number of bone and joint surgeries done in the United States each year. The most recent National Healthcare Safety Network (NHSN) report includes data from 2006 to 2008. This report published knee replacement postoperative infection rates ranging from 0.68% to 1.60%, depending on patient risk, and hip replacement infection rates from 0.67% to 2.4%.[4] If these rates were applied to all of the hip and knee replacements done in the U.S., we could estimate that somewhere between 6,000 and 20,000 SSIs occur annually in hip and knee replacements alone. Estimates of the total number of patients who have SSIs following all orthopedic surgery is somewhere between 31,000 and 35,000. One study estimated that orthopedic SSIs prolong total hospital stays by a median of two weeks per patient, approximately double readmission rates, and increase healthcare costs by more than 300%. Moreover, patients with orthopedic SSIs have substantially greater physical limitations and significant reductions in their quality of life.[5] Infectious complications may range from superficial infections to deep and organ-space infections, many of which may be associated with increased mortality.

State and Federal Initiatives

Consumer demand for public reporting of healthcare quality data has increased since the 1999 publication of the Institute of Medicine's *To Err is Human: Building a Safer Health System*.[6] The report was based upon analysis of multiple studies by a variety of organizations and concluded that between 44,000 to 98,000 people die each year as a result of preventable events such as medication errors, surgical complications and infections. Subsequently, there was demand for greater transparency and a concerted effort to reduce and eliminate HAIs . The development of an HAI is no longer considered an inevitable consequence of healthcare.

After years of debate on both the federal and state levels, mandatory public reporting of HAIs has become a reality in an increasingly large number of states. Additionally, the department of Health and Human Services (HHS) has set specific five-year targets for reducing the incidence of selected HAIs in acute care hospitals. These targets, along with a series of proposed action steps, were published in the *HHS Action Plan to Prevent Healthcare-Associated Infections*. (www.hhs.gov/ophs/initiatives/hai/actionplan/index.html). The campaign targeted the four categories of infections that account for approximately three-quarters of HAIs in the acute care hospital setting:

1. SSIs
2. central line-associated bloodstream infections (CLABSIs)
3. ventilator-associated pneumonia (VAP)
4. catheter-associated urinary tract infections (CAUTI)

Clostridium difficile disease (CDAD) and methicillin-resistant *Staphylococcus aureus* (MRSA) have also been added to the priority list. Additionally, further work will include Ambulatory Surgery Centers (ASCs) as part of the Tier Two Action Plan.

On July 30, 2010, a rule released by the Centers for Medicare & Medicaid Services (CMS) laid out HAI reporting requirements for Medicare eligible hospitals that participate in CMS's pay-for-reporting program. More than 3,500 hospitals will be required to use the U.S. Centers for Disease Control and Prevention (CDC)'s NHSN to report CLABSI and SSI data to CMS. The SSI reporting will begin October 2012 for 2014 payment. Specifics related to procedures have not yet been determined. Nevertheless, it is clear that prevention of SSIs is a top clinical, administrative and political priority, and that orthopedic infections comprise a large portion of these infections.

Incidence, Scope & Epidemiology

Incidence of SSIs Following Hip, Knee, and Spine Procedures

According to the NHSN report, a large U.S. database for HAI aggregation and comparison report titled: "Data Summary for 2006 through 2008," issued December 2009, SSI rates for hip replacement, knee replacement, open fracture reduction, spinal fusion, and laminectomy procedures are as follows:

Table 1: Pooled means of SSI rates by operative procedure and risk index categories, 2006 through 2008[7]

Procedure	Inpatient or Outpatient	Risk Index Category	Number of Procedures	Number of SSIs	Pooled Mean
Spinal fusion	Inpatient	0	20,059	140	0.70
Spinal fusion	Inpatient	1	16,640	306	1.84
Spinal fusion	Inpatient	2,3	4,511	187	4.15
Open reduction of fracture	Inpatient	0	3,600	40	1.11
Open reduction of fracture	Inpatient	1	5,629	100	1.78
Open reduction of fracture	Inpatient	2,3	1,249	42	3.36
Hip prosthesis	Inpatient	0	49,576	334	0.67
Hip prosthesis	Inpatient	1	65,046	938	1.44
Hip prosthesis	Inpatient	2,3	15,769	379	2.40
Knee prosthesis	Inpatient	0	70,675	409	0.58
Knee prosthesis	Inpatient	1	79,653	786	0.99
Knee prosthesis	Inpatient	2,3	20,855	333	1.60
Laminectomy	Inpatient	0	20,972	150	0.72
Laminectomy	Inpatient	1	15,054	166	1.10
Laminectomy	Inpatient	2,3	4,051	93	2.30
Knee prosthesis	Outpatient	0,1,2,3	16	0	0.00
Laminectomy	Outpatient	0,1,2,3	901	7	0.78

Research Related to Incidence, Morbidity, Mortality, and Cost

SSIs following clean orthopedic procedures, such as joint replacement and certain spinal procedures, have become increasingly rare since evidence-based practices related to skin preparation, surgical technique, and antibiotic prophylaxis have become the accepted standard of care in orthopedic surgery.

However, the adverse outcome of SSIs related to a clean orthopedic surgical procedure continues to be associated with significant morbidity, cost, and even mortality. The patient's functional status may also be adversely affected by an orthopedic SSI.

Various researchers have published data related to incidence, morbidity, mortality, and cost. Many reports describe outcomes for a specific orthopedic procedure, but some include a variety of procedures in their study.

Pollard et al. determined that hip fracture patients, treated with either fixation or hemiarthroplasty, developed infection-accrued costs three times greater than those of non-infected control patients ($38,000 versus $11,255). Costs were also higher for infections caused by MRSA as opposed to methicillin-susceptible strains. Although not

statistically significant, there was a decreased likelihood of patients with infection surviving to discharge from the hospital. Of borderline significance was the finding that patients with infection were less likely to return to their pre-fracture residence.[8]

Using a multivariate logistic regression analysis, Veeravagu et al. studied patients undergoing spinal decompression and fusion. In a study of 24,774 patients' data from the Veteran's Administration Surgical Care Improvement Project (SCIP) database, an incidence rate of 3.04% was calculated. Other findings included an extended hospital stay (7.12 days for infected patients versus 4.20 days for non-infected controls), increased 30-day mortality rate (1.06% versus 0.5%), increased complication rate (1.24% versus 0.05%) and an increased return to surgery rate (37% versus 2.45%).[9]

Kuper, in 2008, published a literature review of research articles related to total knee and hip replacement SSIs. His findings include an annual cost of total joint replacement infections in the U.S. of $250 million. Cost of revision of a total joint due to infection is 2.8 times higher than cost of revision for aseptic loosening, and 4.8 times higher than costs associated with primary total hip arthroplasty. The cost of total knee arthroplasty revision due to infection ranges from $15,000 to $30,000. Total hip arthroplasty revision due to infection results in significantly more hospitalizations, total length of stay, number of operative procedures, outpatient visits and charges, and additional complications than revision due to aseptic loosening of the prosthesis.[10]

Lee et al. studied outcomes for a variety of orthopedic procedures, including hip and knee replacement, open reduction of fracture, other joint replacement, spinal fusion and laminectomy. Patients older than 64 years of age were included in her two-nested case control study, and infections were either deep incisional or organ space, per CDC definitions, requiring operative debridement. Of the 15,218 procedures reviewed, 169 infections were studied. There were 171 controls. Statistically significant findings included a higher one-year postoperative mortality (17% versus 4%), increased length of stay, including readmission within 90 days of surgery (13 versus four days), and a mean of 9.31 days of hospitalization attributable to infection.[11]

Olsen et al. conducted a retrospective case control study of patients who had either laminectomy or spinal fusion procedures. Forty-one patients with SSI or meningitis were compared to 178 uninfected patients. Of the patients with SSI, all received additional antibiotic therapy, 30 (77%) underwent re-operation due to their infection, and 30 (77%) were re-hospitalized at least once for wound care treatment. The mean readmission length of stay was 8.5 days (mean 6 days, range 0-45 days).[12]

Whitehouse et al. studied patients undergoing a variety of orthopedic procedures, including open reduction of fracture, fusion, laminectomy and joint replacement. The methodology used was a pairwise matched (1:1) case-control study within a cohort. Of 59 case patients, 11 (19%) were patients who had undergone joint replacement surgery. Findings that reached statistical significance included increased median initial length of stay, total number of hospitalizations, number of surgical procedures, total length of stay, and cost. Although the mortality rate was higher among patients who experienced infection, that finding did not achieve statistical significance. Whitehouse also addressed the quality of life issue, using a questionnaire that was completed by 62% of study participants. Patients with SSIs reported substantial reductions in the quality of life measures one year after the initial procedure, compared to non-infected control patients.[13]

Partanen studied deep wound infections in patients who underwent hip procedures, including repair with screws, hemiarthroplasty, total arthroplasty, and gamma nail repair. Of 2,276 patients older than 50 years of age, 29 (1.3%) experienced deep infection requiring surgical revision. These cases were matched with controls who did not experience infection. Greater rates of impaired function and mortality were noted, although neither of these findings achieved statistical significance.[14]

Lentino reported an estimated cost of treating an infected arthroplasty of more than $50,000 and a mortality rate that was double that of uninfected patients during the first three months following arthroplasty.[15]

Wilson reviewed infection rates in 125 English hospitals from April 2004 through March 2005 and noted an infection rate of 1.26% following total hip replacement procedures and a rate of 4.06% following hemiparthroplasty. Of statistical significance was the finding that SSI risk was greater following revision procedures than following the primary operation.[16]

Epidemiology of, and Risk Factors for, Orthopedic SSI

Epidemiology is defined as the study of health-related events in defined populations, observing specific illnesses and conditions and the exposures and host factors that may be associated with their occurrence. The diseases or conditions may be infectious or non-infectious.[17] Epidemiologic investigations of infectious diseases can lead to a better understanding of the pathogenesis of infection, and ultimately to improved and evidence-based prevention and control strategies.

The rates of SSI following various orthopedic procedures appear to be increased when certain risk factors are present. Risk factors can be either patient- or procedure-specific, and may be modifiable or non-modifiable.

With regard to clean spinal procedures, risk factors that have been associated with increased SSI include estimated blood loss of greater than one liter, previous SSI at the operative site, diabetes, obesity, longer procedure times (more than five hours), current smoking, ASA score of three or more, weight loss, dependent functional status, preoperative hematocrit of less than 36, disseminated cancer, elevated preoperative or postoperative serum glucose level, suboptimal timing of antibiotic prophylaxis, and two or more surgical residents participating in the operative procedure. Additionally, posterior approach or combined anterior/posterior approach were associated with higher rates of infection.[18,19,20,21]

For knee replacement procedures, factors associated with increased risk of postoperative wound infection include male gender, rheumatoid arthritis or fracture as indication for arthroplasty, low volume of cases performed by the operating surgeon, morbid obesity, and diabetes.[22,23,24]

Risk factors associated with higher rates of infections following clean hip procedures include undergoing arthroplasty surgery in a hospital with low volumes of arthroplasty procedures and prolonged wound drainage following the procedure.[25,26] Edwards, in a 2008 study conducted in England, found no statistically significant preoperative risk factors for infection following hip surgery.[27]

Various researchers have studied infection rates in both hip and knee procedures. The factors identified that are associated with increased risk of infection in either of these procedures are diabetes and greater number of medical comorbidities (at least three).[28,29]

A 2010 study of orthopedic procedures in general demonstrated that nasal carriage of *Staphylococcus aureus* increases the risk of *Staphylococcus aureus* wound infection following orthopedic surgery[30] and that admission from a healthcare facility increases the risk of orthopedic SSI.[31]

In summary, a variety of patient or host- and procedure-associated factors appear to be associated with increased risk of infection following orthopedic surgery. The following table summarizes those factors, including potential for modification of each factor:

Table 2: Modifiable and Non-Modifiable Host- and Procedure-Related Orthopedic SSI Risk Factors

	Modifiable	Non-Modifiable
Host-specific	Obesity Current smoking Hematocrit < 36 Elevated preoperative or postoperative serum glucose Nasal carriage of *Staphylococcus aureus* (as risk factor for *Staphylococcus aureus* infection)	Diabetes Male gender Rheumatoid arthritis ASA score of 3 or greater Recent weight loss Dependent functional status Disseminated cancer Admission from a healthcare facility
Procedure-specific	Estimated blood loss of > 1 liter* Longer procedure time* Suboptimal timing of prophylactic antibiotic Two or more surgical residents participating in procedure Prolonged wound drainage* Spinal procedure via the posterior or the anterior/posterior approach	Estimated blood loss of > 1 liter* Longer procedure time* Previous infection at site Prolonged wound drainage* Low volume of procedures performed at hospital Low volume of procedures performed by surgeon

*These factors may be modifiable if related to surgical technique or non-modifiable if related to a specific and discrete operation. For example, if a particular surgeon consistently has surgical procedure times that are significantly longer than the NHSN average for that procedure, the risk factor of procedure time could be modifiable with changes in the surgeon's practice. However, if the procedure duration of one discrete operation is prolonged due to intraoperative complications, then the risk factor of longer procedure time would be considered non-modifiable for that particular operation.

Most infections at orthopedic surgical sites are diagnosed within the first two postoperative years. Indeed, to be considered an SSI according to CDC NHSN guidelines, the diagnosis must be made within 12 months of the procedure.

Kurtz et al. reviewed a sample of Medicare patients who underwent total knee replacement surgery and noted an infection incidence rate of 1.55% within the first two years after surgery; between years two and 10, the incidence rate was 0.46%.[32]

The same research group reported similar findings in total hip arthroplasty patients a year earlier, using Medicare data as well. The two-year infection rate among this population was 1.63%; for years two through 10, the rate fell to 0.59%.[33]

Pathogenesis

Pathogenesis and Microbiology of SSIs, including Clean Orthopedic Procedures

For all surgical procedures, infection at the operative area has always been recognized as a potential complication. With the advent of antibiotics in the 1940s, this dreaded adverse outcome became less common (or more treatable) and, with recent advances in infection prevention measures, including standardized antimicrobial prophylaxis protocols, even greater reductions in SSI rates have resulted. Nevertheless, infection at the operative site remains a potentially devastating, even fatal, event.

An SSI is similar to all infections, in that it is typically multi-factorial in origin. The occurrence of a postoperative infection is dependent upon the interaction of patient- or host-related factors, such as host immunity, nutritional status, comorbid conditions; procedure-related factors, including the presence of foreign bodies and tissue trauma associated with the procedure; microbial properties, such as ability to adhere to tissue or foreign bodies and innate virulence, and appropriate and timely antimicrobial prophylaxis.

Surgical wounds are classified by the degree of bacterial contamination (or microbial load) at the time of the procedure. Greater microbial loads result in increased infection risk. The CDC classifies wounds as clean, clean-contaminated, contaminated, or dirty in the NHSN patient safety component, SSI data collection. Orthopedic surgical wounds addressed in this document would almost always be classified as clean.

Table 3: Surgical Wound Classification[34]

Classification	Wound Parameters
Clean	• An uninfected operative wound in which no inflammation is encountered and there is no entry into the respiratory, alimentary, genital, or urinary tract • Clean wounds are closed primarily and, if necessary, drained with closed drainage
Clean-contaminated	• Operative wounds in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination • No evidence of infection is encountered or major break in technique occurs
Contaminated	• Open, fresh accidental wounds • Operations with major breaks in sterile technique or gross spillage from the gastrointestinal tract • Incisions in which acute, non-purulent inflammation is encountered
Dirty or infected	• Old traumatic wounds with retained devitalized tissue • Existing clinical infection or perforated viscera is encountered • This definition suggests that the organisms causing postoperative infection were present in the operative field prior to the procedure

Contamination of the surgical wound is almost unavoidable despite the best efforts of the surgical team. The goal in surgical antisepsis is minimization of the bacterial load to the greatest degree possible. Lack of adherence to asepsis by scrubbed personnel or those in close proximity to the sterile field can be a risk factor for development of an SSI.[35] Quantitatively, it has been shown that if a surgical site is contaminated with >105 (100,000) microorganisms per gram of tissue, the risk of SSI is markedly increased. However, the dose of contaminating microorganisms required to produce infection may be much lower when foreign material (i.e.,implants or sutures) is present at the site (i.e., 102 or 100 microorganisms per gram of tissue).[36]

Preparation of the patient's skin is a significant intervention taken to reduce bacterial contamination. However, since as much as 20% of the skin's bacteria are resident (living beneath the epidermal layer of skin, in appendages such as hair follicles and sebaceous glands), any incision made through the skin has the potential of carrying some of this bacterial load directly to the operative site.[37,38] According to the 1999 CDC Guideline for Prevention of Surgical Site Infections, for most SSIs, the source of pathogens is the endogenous flora of the patient's skin, mucous membranes or hollow visera (gastro-intestinal tract). Bacteria can be found on all areas of the body, but are found in significantly higher numbers in those moist areas that include the axilla, skin folds, webs of the feet, perineal area, and peri-anal area.[39]

Environmental factors in the operating environment can play a role in the pathogenesis of infection. The microbial load in the surgical suite is directly proportionate to the number of people in the room.[40] Additionally; nasal carriage of S. aureus has been identified as a major risk factor for wound infections after both orthopedic total joint and cardiac surgery. A study published in 2004 by Wertheim, et al demonstrated that genotyping revealed that 80 percent of S. aureus bacteremia infections were caused by the patient's own clonal nasal flora.[41] In a study done in 2002 by Kalmeijer, et al, it was determined that high-level nasal carriage of S. aureus was the most important and only significant independent risk factor for developing SSI with S. aureus following orthopedic surgery with prosthetic implants.[42]

Investigation of an outbreak of SSIs in knee replacement surgeries in a single operating room, described by Babkin et al. in 2007, implicated environmental factors, including multiple entrances to the operating room with frequent movement through them during procedures; non-standardized horizontal-flow air conditioning installed above the main door to the room; and utilization of a washing sink just beyond the main door for cleaning of instruments during procedures. When the sink was removed, the air conditioning unit was disconnected, and the door was locked during procedures, the infection rate fell from 5.6% to 2.2%.[43] Likewise, issues such as contamination or inadequate sterilization of instruments, are also an important risk factor for development of infection. Inadequate sterilization of surgical instruments has resulted in SSI outbreaks.[44]

Microbiologic and Virulence Factors

Orthopedic surgery frequently involves placement of a foreign body, either a prosthetic joint, joint components, or hardware used to stabilize bony structures or repair fractures. These implants can facilitate infection by either locally introduced contamination or by hematogenous spread of microorganisms. Locally introduced contamination occurs during the perioperative period. Hematogenous spread of microorganisms is typically an event that happens following the perioperative period, and is associated with primary bacteremia or infection at a distant site with secondary bacteremia, leading to microbial seeding of the prosthetic joint.

Infections that arise due to local contamination are the result of an infection adjacent to the prosthesis or to contamination during the surgical procedure. Delay in wound healing predisposes a patient to wound infection. Ischemic necrosis, infected wound hematomas, superficial wound infection, and suture abscesses may be precursors of deeper SSI. Physical barriers that normally protect the deep joint are interrupted during the surgical procedure, increasing the risk of infection.

Bloodstream infection can result in joint replacement wound infection via the hematogenous route. Thus, a primary bacteremia or an infection at a distant site with secondary bacteremia creates a risk for periprosthetic SSI. It is estimated that 20% to 40% of prosthetic joint infections arise via the hematogenous route.

One researcher cited an SSI rate following total knee replacement surgery attributed to hematogenous spread of at least 50%.[45] For infections that develop more than one year after the procedure, the hematogenous route of infection should be strongly considered.[46]

The specific microbiology of an orthopedic wound infection has an impact on the severity, onset, and even the outcome of infection due to differences in rates of growth, ability to survive in the host environment, and virulence. Biofilm plays a significant role in the pathogenesis of infection, including orthopedic SSIs. Once microorganisms have made contact and formed an attachment with a living host or non-living surface or object, development of a biofilm can take place.[47] Bacteria living in a biofilm can have significantly different properties from free-floating bacteria, as the dense extracellular matrix of biofilm and the outer layer of cells may protect the bacteria from antibiotics and normal host defense mechanisms of the white blood cells, such as phagocytosis.

Microorganisms may contain or produce toxins and other substances that increase their ability to invade a host, produce damage within the host, or survive on or in host tissue. Characteristics of the specific infecting microorganism, particularly related to virulence as well as the ability to adhere to a foreign object such as an implantable device, play a role in the presentation of infection. *Staphylococcus aureus*, one of the most common organisms associated with orthopedic SSIs, can possess a high degree of virulence due to its ability to produce toxins and to develop resistance to many classes of antimicrobial agents. Infections caused by this organism are associated with more rapid onset and poorer outcomes.

Coagulase-negative *Staphylococcus*, another common agent associated with orthopedic infection, readily develops antimicrobial resistance, but often presents later in the postoperative period.

Pseudomonas aeruginosa may be introduced into the bone or joint via direct inoculation during the surgical procedure, hematogenous spread, or spread from a contiguous infection. *Pseudomonas* infection often has a delayed presentation and may become a chronic infection following fracture repair.

Gram-positive organisms predominate in orthopedic SSIs, with coagulase-negative *Staphylococcus* historically being the most common microorganism, followed by *Staphylococcus aureus*, both methicillin-resistant and susceptible. Other organisms that have been isolated from surgical wounds include *Pseudomonas*, *Proteus spp.*, coliforms, enterococci, Group C *Streptococci*, *Serratia marsescens*, corynebacterium, micrococcus, propionibacterium, anaerobes, yeast, mycobacterium, *Listeria*, bacillus, and other gram-negative bacteria. Candida is a rare causative agent in orthopedic SSIs, accounting for approximately 1% of infections.

Distribution of pathogens related to orthopedic surgery is summarized below:
From table 5 Distribution of Selected Pathogens Associated with Cases of Surgical Site Infection Reported to the National Healthcare Safety Network, January 2006-October 2007, by type of Surgery. NHSN Update on Antimicrobial Resistance 2006-2007;1001.[48]

Pathogen	Orthopedic surgery (N = 963)	Pathogen	Orthopedic surgery (N = 963)
Coagulase-negative Staphylococcus	173 (15.3)	Escherichia coli	34 (3.0)
Staphylococcus aureus	548 (48.6)	Pseudomonas aeruginosa	38 (3.4)
Enterococcus Species		Klebsiella pneumoniae	14 (1.2)
E. faecalis	57 (5.1)	Enterobacter species	37 (3.3)
E. faecium	13 (1.2)	Acinetobacter baumannii	10 (0.9)
Not specified	34 (3.0)	Klebsiella oxytoca	5 (0.4)
Candida Species		Total number of pathogenic isolates by surgery type	1,128
Candida albicans	2 (0.2)		
Other or not specified	2 (0.2)		

Staphylococcus aureus was also identified as the major pathogen in hip replacement surgery, as reported in the New York State 2009 Hospital-Acquired Infection Report. There were 186 isolates of *Staphylococcus aureus* reported. This organism accounted for 59.8% of the total isolates. Of these 186 isolates, 102 were methicillin-resistant (55% of all staph, and 32.8% of total pathogens).[49]

Surgical Wound Definitions and Diagnosis

SSIs are well defined by the CDC's NHSN. Surgical procedures can be classified as either inpatient or outpatient. For inclusion in the NHSN database, the surgical procedure must involve an incision through skin or mucous membrane, be performed in an operating room, and be included in the list of NHSN operative procedures. These classifications, although confined to the U.S. NHSN system, have been adapted and widely adopted globally.

Wounds following surgical procedures are classified as superficial incisional, deep incisional, or organ/space, depending upon the tissue or body part involved.

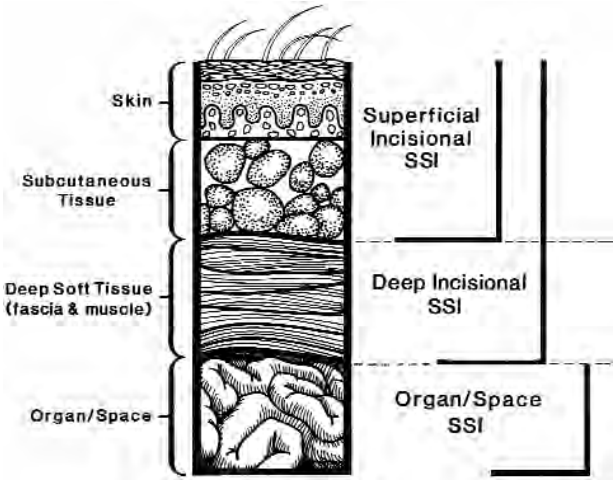


Figure 1: Layers of skin and deep space.

Superficial incisional SSIs must meet the following criteria:

infection occurs within 30 days after the operative procedure
and
involves only skin and subcutaneous tissue of the incision
and
patient has at least one of the following:

a. purulent drainage from the superficial incision
b. organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision
c. at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness or heat, and superficial incision is deliberately opened by surgeon, and is culture-positive or is not cultured (a culture-negative finding does not meet this criterion)
d. diagnosis of superficial incisional surgical by the surgeon or attending physician

Deep incisional SSIs must meet the following criteria:

infection occurs within 30 days after the operative procedure if no implant is left in place, or within one year if implant is in place and the infection appears to be related to the operative procedure
and
involves deep soft tissues (e.g., fascial and muscle layers of the incision)
and
patient has at least one of the following:

a. purulent drainage from the deep incision but not from the organ/space component of the surgical site

b. a deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured when the patient has at least one of the following signs or symptoms: fever (>38°C), or localized pain or tenderness (a culture-negative finding does not meet this criterion)
c. an abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination
d. diagnosis of a deep incisional SSI by a surgeon or attending physician

An organ/space SSI must meet the following criteria:

infection occurs within 30 days after the operative procedure if no implant is left in place, or within one year if implant is in place and the infection appears to be related to the operative procedure

and

infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure

and

patient has at least one of the following:

a. purulent drainage from a drain that is placed through a stab wound into the organ/space
b. organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space
c. an abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination
d. diagnosis of an organ/space SSI by a surgeon or attending physician

Diagnosis of SSI related to clean orthopedic surgical procedures is a complex process, using clinical signs and symptoms, laboratory data, and radiologic findings and /or surgeon or medical officer confirmation or diagnosis.

The clinical presentation of infection is dependent on the properties of the infectious agent (i.e. innate virulence), the nature of host tissue at the site of infection, and the route of infection (locally introduced versus hematogenous spread from a distant site or bloodstream). Inflammatory signs may be variable. Typically, progressive joint pain is a patient complaint, with or without presence of a sinus tract (or tracts) with drainage.

A fulminant presentation is suggestive of infection with a virulent organism, such as *Staphylococcus aureus* or β-hemolytic streptococci. Less virulent, coagulase-negative *Staphylococcus*-related infections present a more delayed course.

Properties of affected tissue affect the clinical presentation due to their ability to support microbial growth. The ability of bacteria to flourish is enhanced in wound hematomas, fresh operative wounds, ischemic wounds, and the tissue of diabetic patients or those on long-term steroid therapy. Size of the infectious inoculum also affects the clinical presentation, with a larger inoculum producing a more toxic picture.

Joint pain is the principal symptom of deep tissue infection, regardless of the mode of presentation. It suggests either acute inflammation of periarticular tissue or loosening of the prosthesis as a result of subacute erosion of the bone at the bone-cement interface. Acute inflammation may present earlier in the postoperative course, while subacute erosion may be associated with later onset infections.

Clinical manifestations of joint pain, swelling, erythema, and warmth all reflect an underlying inflammatory process, but are not specific for infection.

If the presentation of pain at the joint includes fever or purulent drainage from the overlying cutaneous sinuses, infection may be presumed. More often, though, infection must be differentiated from aseptic and mechanical

problems, which are more common causes of pain and inflammation in orthopedic surgical patients. Constant pain or pain at night or rest is indicative of infection (or malignancy); pain of sudden onset that occurs with motion or weight bearing suggests another cause, such as prosthetic loosening. A history of postoperative hematoma or delayed wound healing suggests that joint pain is infection-related.

Laboratory findings of erythrocyte sedimentation rate (ESR) elevation beyond six months after surgery is suspicious for infection. Fulminant infection or infection with secondary bacteremia is more likely to result in the typical infection-related laboratory findings of elevated white blood cell count. Culture of joint aspirate is inconsistently predictive of infection. Barrack and Harris reviewed 270 cases in which aspiration of the hip joint was performed prior to revision surgery. They discovered 32 false-positive aspirations. Of six infected hips, only two aspirations were positive (there were four false-negative aspiration specimens).[50]

In summary, the incidence of orthopedic postoperative SSI varies by the type of surgery and may be influenced by both modifiable and non-modifiable risk factors. Understanding the risks associated with these infections will help the IP and all members of the healthcare team develop strategies to prevent postoperative infections in orthopedic surgeries.

The Infection Prevention Program

An effective infection prevention program for orthopedic surgery has many components. Implementation of, and consistent adherence to, evidence-based practices to reduce the risk of SSI is key to success. However, it is important to conduct a thorough risk assessment and to collect and analyze surveillance data to drive improvements. Surveillance data can provide measurable results to evaluate the effectiveness of infection prevention interventions.

The Risk Assessment

A risk assessment is a systematic evaluation for identifying risks in the healthcare setting. Infection Control assessment identifies risks for acquiring or transmitting infections, and includes strategies for prioritizing and mitigating those risks.
A risk assessment can be either quantitative or qualitative, and can include both process and outcome measures.

Steps for Performing the Risk Assessment:

Create the risk assessment team, ensuring input from key support and clinical departments. The team should gather organizational information and set a timeline for assessment.[51] Current literature and past trends should be evaluated. Example: No less than annually and whenever new risks or procedures are identified.

Questions to consider:

What is the volume of orthopedic surgery?

What are the major procedures performed?

What is the frequency of infections in orthopedic surgery?

What are the major pathogens identified? What is the proportion of multiple drug-resistant organisms?

Are there any new procedures performed?

What is the frequency of readmissions related to postoperative SSIs in orthopedic surgery?

Evaluation of Process Measures:

Are antibiotic prophylaxis criteria, including preoperative timing, antibiotic selection and postoperative duration, part of standing orders and pathways?

Are there standardized procedures for preoperative preparation of the skin that specify the appropriate antiseptic agent(s), and correct application?

Do patients and families receive instructions as to their preoperative, perioperative and post-discharge roles in prevention of SSIs?

Do healthcare workers and licensed independent practitioners receive education upon hire and annually related to prevention of SSIs?

Risk Assessment Type and Template

Example:

Joan directs an infection prevention program in a mid-size community teaching hospital. She has collected data on total joint replacement surgeries using NHSN for the past two years.

Last year, 357 total hip replacements and 240 total knee replacements were performed at her facility. There were seven postoperative hip infections and one knee infection.

Of the seven postoperative hip infections, the pathogens isolated were:

- 5 methicillin-resistant *Staphylococcus aureus* (MRSA)
- 1 coagulase-negative *Staphylococcus*
- 1 methicillin-sensitive *Staphylococcus aureus* (MSSA)

The pathogen associated with the one postoperative total knee infection was also MSSA.

Of the seven hip infections and one knee infection in joint replacement surgery, there were five (5) deep or organ space infections that required surgical intervention. All five SSIs were hip replacements.

There are 10 orthopedic surgeons on staff, but the majority of total joint replacement procedures were performed by seven surgeons who each perform approximately 75-80 procedures annually. The infections are not attributable to a single surgeon and occur sporadically throughout the year.

Appropriate antibiotics are ordered 100% of the time. Timing demonstrates that 98% of patients receive antibiotics in the appropriate time frame. Only 88% of patients have antibiotics discontinued within the recommended 24 hours.

Joan and the team review current literature on prevention practices. A perioperative nurse from the orthopedic service is added to the team.

The risk assessment can be either qualitative or quantitative.

Qualitative Risk Assessment:

The qualitative risk assessment uses an approach that assesses the risk based upon written descriptions. One example is described below:

Sample Gap Analysis – Total Hip Replacement

Areas/ Topic	Current Status	Goals	Identified Gap	Actions	Priority
SSIs in hip replacements	7 actual Infections versus 3.7 expected (NHSN) SSI rates twice the mean in the first two risk categories 5 of the patients required further surgical intervention	Reduce SSIs in hip replacements by at least 30% Improve adherence to discontinuing antibiotics within 24 hours to at least 95%	No standard order sets or pathways for discontinuing antibiotics Knowledge deficits by nursing when IV infiltrates or is interrupted during immediate postoperative period MRSA incidence increased from previous year No standard protocols for addressing patients who may be colonized with MRSA preoperatively	Incorporate orthopedic prophylactic antibiotic protocols into order sets and pathways Develop MRSA screening program for orthopedic surgery Engage stakeholders to develop standard prep procedure	HIGH (rates have doubled since last year)

(continued)

Areas/ Topic	Current Status	Goals	Identified Gap	Actions	Priority
			No standard perioperative prep procedure No standardized practices for warming patients	Incorporate temperature management protocol using active warming, such as forced-air warming, to maintain patient normothermia including prewarming, intraoperative and post-operative warming.	

Source: Linda R. Greene, RN, MPS, Rochester General Hospital, Rochester, N.Y.

Quantitative Risk Assessment

A quantitative risk assessment is one in which a number is assigned to specific pre-determined criteria.[52]

SSIs	Benchmark	High Risk	High Volume	National Initiative	Financial Initiative	Risk Rating
Hip replacement						

Template provided by Shannon Oriola, RN, COHN, CIC, Sharp Metropolitan Medical Center, San Diego, California.

Relative Risk 0-3
3 = High Risk
2 = Moderate Risk
1 = Minimal Risk
0 = No Risk
Score 10 or above = High priority

Using the Tool

The following is a hypothetical example of how the tool may be used, based upon the information obtained in the risk assessment example described above:

1. **Benchmark** – Rates of SSIs in hip replacement surgery are above the NHSN mean, but not by a statistically significant difference. This was considered a moderate risk. Risk score = 2
2. **High Risk** procedure or activity – Patients who develop SSIs may require removal of the prosthesis. Only 88% of patients have antibiotics discontinued within the recommended 24 hours, and there is a high proportion of MRSA in patients who develop an SSI. This was considered high risk. Risk score = 3
3. **High Volume** – Hip replacements are a high-volume procedure in this organization. It is the third highest volume procedure performed, and therefore was identified as a high risk. Risk score = 3
4. **Potential Negative Outcome** – SSIs in hip replacements are associated with increased morbidity, mortality and length of stay. Five patients last year developed deep or organ space infections requiring surgical intervention. Risk score = 3

5. **National Initiative** – At the time of the risk assessment, there is not a national initiative associated with outcome measures in orthopedic surgery. Risk score = 0
6. **Financial Incentive** – The cases involved an average of 7-10 days increased length of stay and an excess average cost per case of $ 32,000. Risk score = 3

SSIs	Benchmark	High Risk	High Volume	Potential Negative Outcome	National Initiative	Financial Initiative	Risk Rating
Hip Replacement	**2**	**3**	**3**	**3**	**0**	**3**	**14**

Evaluation

Since this procedure is above the 10-point risk priority ranking, it will be part of the annual infection prevention plan. It is important to set goals and expectations as well as strategies for achieving the goals.

Set Goals and Expectations

Reduce SSI in total hip replacements by at least 30%.

Improve adherence to discontinuing antibiotics within 24 hours to at least 95%.

Actions

Develop MRSA screening program for orthopedic surgery.

Engage stakeholders to develop standard prep procedure.

Incorporate orthopedic prophylactic antibiotic protocols into order sets and pathways.

The above risk assessments use NHSN surveillance criteria. Organizations that do not use NHSN may use overall data collected from surveillance activities. As an alternative, if no surveillance data exists, administrative data may be utilized to assist in case findings. This data cannot be compared to NHSN means, but may be helpful to assist in determining the overall scope of the issues. Likewise, microbiology data may be helpful in determining pathogen frequency and occurrence.

Surveillance

Surveillance is a systemic and ongoing method of data collection, presentation and analysis, which is then followed by dissemination of that information to those who can improve the outcome.

In a healthcare setting, information obtained from surveillance of HAIs can be extremely important in the context of continuous quality improvement as objective data is used to improve patient outcomes.

Surveillance helps to:

- determine baseline rates of adverse events (including HAIs);
- detect changes in the rates or distribution of these events;
- facilitate investigation of significantly increased rates of infection;
- determine the effectiveness of infection prevention and control measures;
- monitor compliance with established hospital practices;
- evaluate changes in practice;
- identify areas where research would be beneficial.

There are many factors to consider when designing an orthopedic surgery surveillance program. The first steps are defining the population at risk and determining the resources available. For example, based upon the risk assessment, consider whether all orthopedic surgeries will be monitored or if just selected procedures such as total hip surgeries or total knee surgeries will be followed. Often, if opportunities for improvement are identified in one procedure, such as total hip replacements, then process improvement activities that are identified can be applied to the service as a whole. Criteria used to conduct surveillance must remain consistent.

Case Finding Methodology

The case finding methodology may depend on what resources are available and may include:

1. wound culture reports
2. operating room reports
3. admission and readmission diagnosis
4. antibiotic lists
5. administrative data; coding data associated with infection codes
6. medical record reviews
7. data obtained from healthcare providers, i.e., surgeon or nursing reports
8. post-discharge surveillance data

Surgical Surveillance

- The numerator for the rate calculation is the number of SSI events.
- The denominator for the rate calculation is the number of surgical cases during that same time frame.

SSI Surveillance Denominator

A count of the specific surgical procedures performed per month is necessary to calculate the SSI rate in a facility. Electronic medical record documentation and operating room records can generally provide a report of the number of patients each month. If this is not available, a manual count must be done of the number of patients undergoing the specific surgical procedure.

SSI Surveillance Numerator

All patients having a selected procedure are monitored for signs of SSI. This surveillance can be done prospectively and retrospectively at the time that criteria is reviewed and evaluated.

SSI Surveillance Methods

The primary methods for determining a baseline rate of SSI is to utilize the NHSN methodology and definitions for SSI. By using NHSN methodology to determine the rate of SSI, cases are risk-stratified by the type of surgery and are also compared to the rates of participating NHSN hospitals.

NHSN Denominator Data

A description of the NHSN surgical component can be accessed at: www.cdc.gov/nhsn/PDFs/pscManual/9pscSSIcurrent.pdf

The following provides a brief description:

An NHSN procedure is one which:

- is performed on a patient who is an NHSN inpatient or an NHSN outpatient
- takes place during an operation where a surgeon makes at least one incision through the skin or mucous membrane, including laparoscopic approach, and closes the incision before the patient leaves the operating room
- includes one of the NHSN procedure categories:

Example of select orthopedic operative procedure categories:

Procedure	Description	ICD 9 codes
Knee prosthesis	Arthroplasty of knee	00.80-00.84, 81.54, 81.55
Hip prosthesis	Arthroplasty of hip	00.70-00.73, 00.85-00.87, 81.51, 81.53
Open reduction of fracture	Open reduction of fracture or dislocation of long bones that requires internal or external fixation; does not include placement of joint prosthesis	79.21, 79.22, 79.25, 79.26, 79.31, 79.32, 79.35, 79.36, 79.51, 79.52, 79.55, 79.56

Specific denominator information for the operative procedure includes demographic and procedure information, such as patient identifier, date of birth, date of procedure, procedure code or ICD 9 code, surgical wound class, length of time for surgical procedure, ASA score, trauma, emergency or elective case.

NHSN surgical methodology is:

- active
- patient-based
- prospective

- retrospective
- priority-directed
- risk-adjusted, incidence rates

NHSN Risk Stratification:

> The index used in NHSN assigns surgical patients into categories based on the presence of three major risk factors:
>
> 1. Operation lasting more than the duration of cut point hours, where the duration cut point is the approximate 75th percentile of the duration of surgery in minutes for the operative procedure, rounded to the nearest whole number of hours.
> 2. Contaminated (Class 3) or Dirty/infected (Class 4) wound class.
> 3. ASA classification of 3, 4, or 5.
>
> The patient's SSI risk category is simply the number of these factors present at the time of the operation.

The collection of infection data should be overseen by a trained or certified IP and/or by an infectious disease physician. The IP shall seek out infections during the patient's stay by screening various data sources (i.e. micro reports, patient records, clinical notes, etc.).

As NHSN methodology requires that surveillance for SSIs is done for up to 30 days following the procedure, and up to one year for surgeries involving implantables, post-discharge surveillance is needed.

Orthopedic SSI Worksheet

Procedure _____
Patient name_____ Medical record or ID _____
Type of infection? Superficial_____ Deep _____ Organ space_____
Radiological evidence of infection _____
Date of surgery_____ Surgeon _____
Purulent drainage? Yes/No. Antibiotic therapy? Yes/No. Antibiotic_____
Pain _____ Redness_____ Other symptoms_____
Type of implant if applicable_____ Blood loss_____ Transfusion? Yes/No.
Date of infection_____ Date of admission to hospital_____
Culture data # 1 date_____ Pathogen_____ Other culture data_____
Date of readmission if applicable _____ Readmission diagnosis _____
Opened at bedside or I and D by surgeon _____
Return to surgery? Yes/No. Date _____
Physician diagnosis of SSI? Yes/No.
If yes, by whom: Surgeon Medical Attending Hospitalist ED Physician Other
Notes _____

Medical history_____ History of MDRO _____
Diabetes? Yes/No. Smoker? Yes/No. BMI_____ Other risk factors_____
Drains (list) _____

Process measures:
Preoperative antibiotic _____ Dose _____
Administered within 1 hour (2 hours for vancomycin) Y_____ N _____
Time _____
Tourniquet time (if applicable) _____
If not on time: Not documented_____ Early _____ Late _____
Antibiotic discontinued within 24 hours? Yes/No. If no, why? _____
Pre-op shower or skin cleaner: identify _____
Hair removal Yes/No. If yes, clip? Yes/No.
Postoperative temperature Greater than or = to 36 degrees C _____
Documentation of patient education on SSI prevention? Yes/No.
Identified opportunities for improvement _____

Worksheet provided by L.Greene RN, MPS,CIC and M. Vignari, RN,CIC Rochester General Hospital Rochester, NY

Electronic Surveillance

Although it is beyond the intent of this guide to discuss electronic surveillance or data mining, a number of facilities rely heavily on these systems to assist in case findings. These systems have the ability to pull essential clinical information for individual patients from hospital data sources throughout the facility. A number of commercial and facility programs interface with a pharmacy database to track antibiotic usage as well.[53] Some commercial programs have the capability to allow the IP to upload denominator and numerator data into NHSN.

NHSN requires that surgical denominator data as well as numerator data be entered into the database to allow for appropriate risk adjustment. The NHSN will allow importation of procedure data in an ASCII comma delimited text file format. The reports can be obtained from different external sources, such as databases or hospital information systems, and imported into NHSN. Steps are described in NHSN and can be accessed at: www.cdc.gov/nhsn/PDFs/ImportingProcedureData_current.pdf.

Data Collection

Criteria used to define the outcome should reflect generally accepted definitions. The best way to determine whether an infection has occurred is to use NHSN criteria, regardless of whether the facility participates in NHSN reporting. This methodology is widely accepted as the gold standard for surveillance and is validated and reliable. NHSN definitions were discussed in a previous section. It is important that strict adherence to definitions be followed, especially when data is used for public reporting purposes in order to ensure consistency across organizations. Additional clinical findings may be appropriate for care and treatment decisions but are not appropriate for surveillance purposes due to variations among healthcare providers and organizations.

Post-discharge Surveillance

There is no gold standard for post-discharge surveillance. Most cases of healthcare- associated SSIs appear after discharge from the hospital. Rates of post-discharge SSI between 2% and 14% have been reported in a number of articles suggesting that organizations with active post-discharge surveillance systems will report higher rates of infection. The 2009 New York State Report for Hospital-Acquired Infections notes that post-discharge surveillance rates are highly variable and are dependent upon resources, technology, and the time frame in which data is collected.

Since most deep and organ space infections require readmission, the 2009 state report does not include any infections detected by post-discharge surveillance that do not require readmission to a hospital. They note that this issue needs further evaluation.[54] Platt described automated surveillance methods based on pharmacy and financial claims data and reported that they are more sensitive for detection of post-discharge SSI.[55] Prospero et al. concluded that certain procedures, such as breast surgery, hernia repair and other endocrine surgery may be at higher risk for post-discharge SSI, and that post-discharge surveillance should be targeted at specific procedures.[56] One major challenge relates to free-standing ASCs and the new CMS requirements. With increasing numbers of orthopedic procedures performed in ASCs, the new CMS requirement to "identify infections" means that all ASCs must implement a working surveillance system for SSIs if one is not already in place. Such surveillance in ASC facilities, by definition, means post-discharge surveillance.

Methods utilized by facilities include:

1. line lists of patients undergoing surgical procedures who are sent to respective surgeons and returned on a regular basis (usually monthly)
2. follow-up phone calls to patients
3. outpatient culture reports
4. readmission data to hospital or to another hospital
5. self reporting by surgeons
6. outpatient reports of antibiotic usage data

Example: Surgeon Post-discharge List
Month: January 2010
Surgeon: John Smith

Name	DOB	Procedure	Procedure date	Infection Y/ N	Antibiotic Y/N (list)	Comment
Doe, John	12/11/54	Total knee	1/4/10			

Please complete last three columns.
Return to Infection Prevention Department, Rosewood General Hospital.

Example: Phone call to patient

Instructions:
The hospital call center will contact the patient between the hours of 11 a.m. and 7 p.m. A phone call is made 30 days after surgery. Three attempts will be made to contact the patient.

Patient Name: Jane Doe
MR: 111111
Date of Surgery: 01/25/10
Procedure: Laminectomy
Phone Number : (xxx) xxx-xxxx

1. Have you followed up with your doctor?

2. Has he or she prescribed any antibiotics for you? If so, what was the reason for the antibiotics?

3. Did you have any drainage from the incision?

4. Describe the drainage.

5. Any pain or redness? Fever?

6. Were you admitted to the hospital or any other hospital since your last surgery? If so, why?

7. Did your surgeon open or drain your incision in his office?

Patient: Return to Infection Prevention Department.

Infection Prevention Department: Evidence of purulent drainage, antibiotics to treat suspected infection, deliberate opening of wound, or readmission to another hospital with complications of surgery will require follow-up with surgeon.

Infection Prevention Department to Complete:

Meets criteria: Y N
If yes, complete postoperative case report.

Outcome Reports

Infection Rate

The numerator (the number of SSIs) and the denominator (the total number of procedures performed) should be calculated on a routine basis and expressed as a percentage by x number of procedures. It is important that the numerator includes all cases performed in a given timeframe and the denominator includes all cases in that same time frame. The surgery date, rather than the infection date, is used for the numerator data. Although some organizations continue to calculate rates based on degree of wound contamination (all class 1) or by service, the most accurate data is SSI calculated by procedure type.

Example:

There were 104 total knee replacements performed in January; 160 in February; 120 in March; and 118 in April. There was one SSI in knee replacement surgery identified during those four months. The case is described below:

Mrs. X was admitted on April 15 with fever and purulent drainage from her knee. Her original surgery was performed on January 16. Radiological results show a collection of fluid around the prosthesis and a possible abscess. The surgeon has documented that she has a postoperative infection and she is taken to surgery for debridement and removal of her prosthesis on April 17. In this example, the monthly SSI rate would be calculated as follows:

Knee Replacements

Month (2010)	Number of surgeries performed	Number of infections	Rate
January	104	1*	1%
February	160	0	0
March	120	0	0
April	118	0	0

* Although the infection was identified in April, the surgery was performed in January.

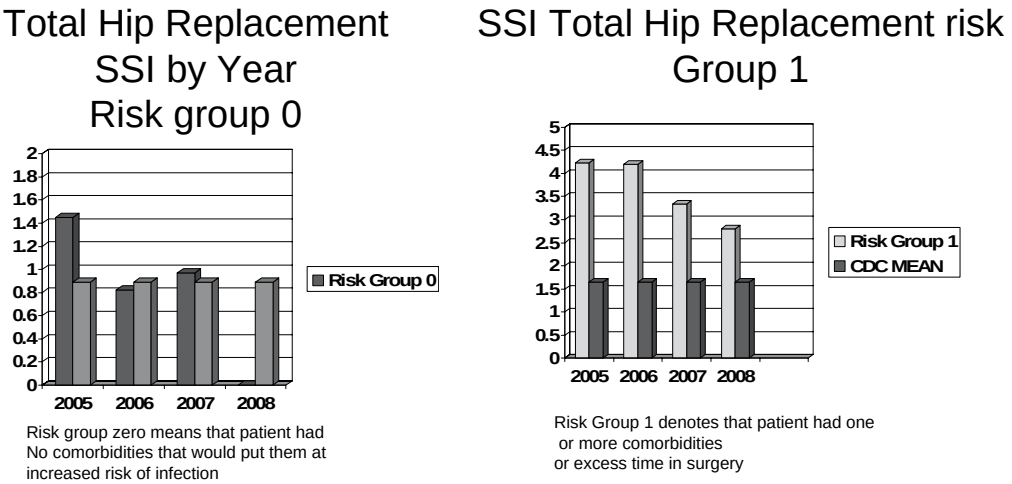


Figure 2

Standardized Infection Ratio (SIR)

This indirect standardization method accounts for differences in the risk of SSIs among a group of procedures.[57]

An SIR is the number of observed infections divided by the number of predicted infections. The expected number is based on the national average, the number of procedures performed by a hospital, and historical data for those procedures. This method is helpful when small numerators and denominators are present.[58]

- An SIR of **1.0** means the observed number of infections is equal to the number of expected infections.
- An SIR **above 1.0** means that the infection rate is higher than that found in the "standard population." For HAI reports, the standard population comes from data reported by the hundreds of U.S. hospitals that use the NHSN system. The difference above 1.0 is the percentage by which the infection rate exceeds that of the standard population.
- An SIR **below 1.0** means the infection rate is lower than that of the standard population. The difference below 1.0 is the percentage by which the infection rate is lower than that experienced by the standard population.

Example: Total Hip Replacement

Year	Number of infections	Number of infections expected	SIR calculation
2007	7	3.74	7/3.74 = 1.87
2008	6	3.7	6/3.70 = 1.49
2009	1	3.8	1/3.80 = 0.26

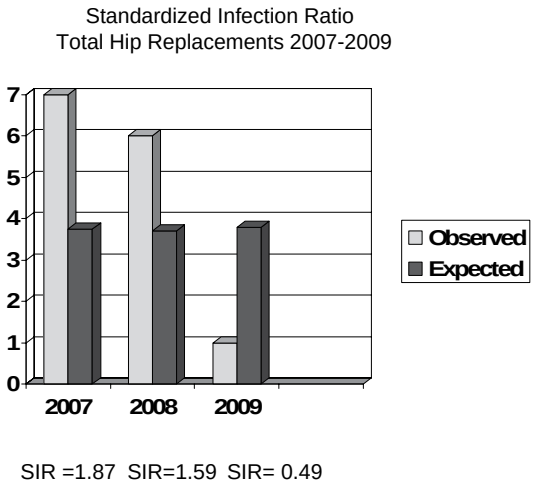


Figure 3

Disseminating Data

One of the most important aspects of surveillance data is the analysis and dissemination of data. Line lists are helpful in providing nursing staff, surgeons and other members of the healthcare team with valuable information. Case information should be disseminated as soon as possible to allow for case reviews. Many organizations post infection rates in prominent areas. One method of displaying data is to calculate the number of cases between infections. Although this method is not useful for inter-hospital comparisons, it provides a useful tool, which is easily understandable by staff. Goals can be set based upon the volume of cases. Process control charts, bar charts and other visual feedback provide methods to display data.

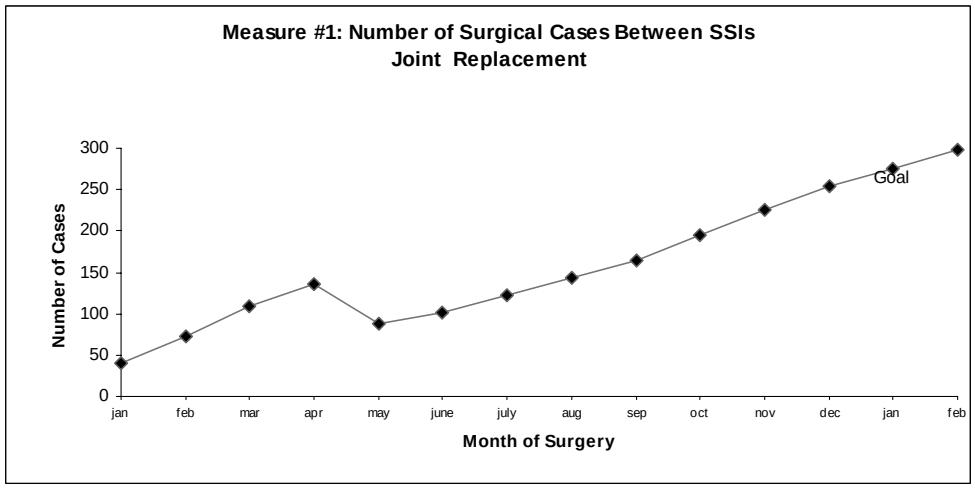

Measure #1: Number of Surgical Cases Between SSIs
Joint Replacement
Number of Cases
300
250
200
150
100
50
0
Goal
jan
feb
mar
apr
may
june
july
aug
sep
oct
nov
dec
jan
feb
Month of Surgery

Figure 4

Surgical Care Improvement Project (SCIP) & CMS Value-Based Purchasing

In 2006 in the U.S., SCIP was launched as a national initiative to reduce postoperative morbidity and mortality by 25% by the year 2010. SCIP is a national partnership of organizations committed to improving the safety of surgical care through the reduction of postoperative complications. Initiated by CMS and the CDC, the SCIP partnership is coordinated through a steering committee of 10 national organizations. More than 20 organizations provide expertise to the steering committee through a technical expert panel. The project's steering committee is composed of members from the following national organizations:

- Agency for Healthcare Research and Quality
- American College of Surgeons
- American Hospital Association
- American Society of Anesthesiologists
- Association of periOperative Registered Nurses
- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services
- Department of Veterans Affairs
- Institute for Healthcare Improvement
- The Joint Commission on

The SCIP was initially composed of four prevention modules: infection, venous thromboembolism (VTE), cardiac and respiratory. The infection prevention component addressed six separate core measures, including delivery of prophylactic antibiotic within one hour prior to incision, appropriate prophylactic antibiotic selection, antibiotic discontinuation within 24 hours post-op (cardiac surgery was given a 48-hour window), glycemic control in cardiac patients (measured by controlled 6 a.m. postoperative serum glucose), appropriate hair removal and normothermia. In order to meet the current CMS Normothermia Measure (SCIP-Infection-10), active warming must be used intraoperatively or achieve the target temperature of ≥36˚C within 30 minutes before or 15 minutes immediately after anesthesia end time. This measure applies to all acute care surgical patients, regardless of age, undergoing general or neuraxial anesthesia for 60 minutes or longer.[59]

1. Specifications Manual for National Hospital

CMS is continuing to implemented incentives for acute care hospitals to collect and report levels of adherence with SCIP measures. In 2011 CMS will encourage hospitals to report certain HAI events, i.e. CLABSI as part of their Hospital Inpatient Quality Reporting Program (formerly Reporting Quality Data for Annual Payment Update (RQDAPU) Facilities that choose not to report select events would accept a 2% reduction in reimbursement by CMS. In 2012 this incentive will include SSIs following select procedures. The roster of procedures remains in development but may include certain orthopedic procedures. Prior to the SCIP initiative, the antibiotic measures were part of the Surgical Infection Prevention (SIP) initiative; they have long been thought to be the cornerstone of good surgical infection prevention.

However, a recent investigation using a retrospective analysis of 405,720 patients from 398 hospitals failed to document an association between adherence to selective SCIP process measures and occurrence of postoperative SSIs. Furthermore, the authors documented an increase in SSIs, despite an improvement in SCIP compliance over a two-year study period.[60] However; adherence measured through an "all-or-none" composite infection prevention score was associated with a lower probability of developing a postoperative infection. This would suggest that the complexity of the surgical procedure requires a comprehensive team-based approach that is inclusive but not limited to a few process measures. Of note, this investigation used claims/administrative data to define SSI. Claims data is not as precise as epidemiologic criteria such as that used by NHSN or NSQIP. Therefore one remaining question is whether in significant reduction in SSI rates using epidemiologic SSI criteria.

The following strategies are examples of methods to increase compliance to antibiotic prophylaxis:

1. provide visual reminders, checklists, and antibiotic prophylaxis as part of the "time out." A study by Wax et al. demonstrated very high rates of compliance when a visual electronic interactive reminder was added to the anesthesia electronic record.[61]
2. incorporate documentation of prophylaxis into electronic documentation forced field functions.
3. incorporate antibiotic selection and duration into order sets and pathways.
4. provide feedback to care providers, on both an individual and overall aggregate level.

Examples of Feedback:

SHARP Memorial Hospital

September 5, 2010

_____, M.D.
Anesthesiology Service Medical Group
3626 Ruffin Road
San Diego, CA 92123

Dear Dr. _____,

The Medical Executive Committee has requested that the Infection Prevention Department monitor the administration of preoperative prophylactic antibiotics for total hip/knee arthroplasty procedures and provide feedback to surgeons and anesthesiologists should our department identify missed opportunities for the optimal use of prophylactic antibiotics.

Enclosed is a copy of the Anesthesia Record (MR# _____) and Visit #(_____) that documents the administration of cefazolin 2 grams at 0804 with the operative procedure start time of 0851 and completed at 1242.

Generally, if an operative procedure exceeds the half-life of the antibiotic, then a repeat dose is given. The half live of cefazolin is 3-4 hours; therefore, a repeat dose before 1204 would have been ideal. It is the time that the antibiotic is initially given and not the incision time that determines when the antibiotic is redosed.

Thank you for your attention to this matter. We appreciate your efforts to further minimize the risk of post-operative surgical site infections.

Sincerely,

Hospital Epidemiologist

Example provided by Shannon Oriola , RN, COHN, CIC Sharp Memorial Hospital, San Diego, California.

Providing individuals with feedback related to process measures is an important component. The following example provides process measure feedback:

SHARP Memorial Hospital

SHARP Memorial Hospital

July 19, 2010

Doctor
Address
San Diego, CA

Dear Dr. xxx :

The Peer Review Oversight Committee of the Medical Executive Committee has requested that the Infection Prevention Unit produce annual surgeon-specific data on adherence to the recommended choice of pre-operative prophylactic antibiotic and to duration of antibiotic administration for designated surgical procedures. This information will be reviewed as part of the re-credentialing process. Optimal use of prophylactic antibiotics decreases the risk of post-operative surgical site infections[1,2]. Infection Prevention is reporting data on hip and knee arthroplasties performed between January 1, 2009 and December 31, 2009.

For this report, the choice of cefazolin, clindamycin or vancomycin was considered appropriate and the presence or absence of allergies was not considered.

Listed below are yours rates (number of cases adhering to guidelines/total number of opportunities) and compared to the rates for 2009 SMH surgeons performing these procedures.

Quality Measure	Your Rates 2008	Your Rates 2009	SMH Surgeons 2009
ABX Choice			**99.8% 617/618**
Duration ≤ 24hrs			**99.7% 616/618**
Preop Nasal Screening			**98.5% 609/618**

Surgeon specific information: **[cases that feel out]**

The following are accepted guidelines:

For initial preoperative prophylaxis:

- Infuse cefazolin 2 grams within 1 hour of the incision.
- For cephalosporin allergic individuals, those with type I hypersensitivity reactions to penicillin, or those colonized with MRSA, use vancomycin 15mg/kg given over 60– 90 minutes and within 2 hours of incision.
- For patients allergic to cephalosporins and vancomycin, use clindamycin 600mgs infused within 1 hour of incision.

If the procedure is longer than 3-4 hours after initial antibiotic **infusion, NOT incision**, 1-2 grams of cefazolin, or for allergic individuals, 600mgs of clindamycin is recommended.

The duration of prophylaxis should be ≤ 24 hours from initial dose.

Thank you for your cooperation. If you need clarification, please contact us at raymond.chinn@sharp.com or judith.vargo@sharp.com.

Sincerely,

Robert Tonks, M.D.
Chief, Orthopedic Supervisory Committee

Raymond Chinn, MD
Hospital Epidemiologist

cc: Peer Review Oversight Committee

[1] Classen DC, Evans RS, Pestotnik SL, Menlove RL and Burke JP, The Timing of Prophylactic Administration of Antibiotic and the Risk of Surgical-Wound Infection. NEJM 326:281-286
2 Bratzler DW, Houck PM. Antimicrobial Prophylaxis for Surgery: An Advisory Statement from the National Surgical Infection Prevention Project. Clin Infect Dis June 15, 2004;38:1706-1715

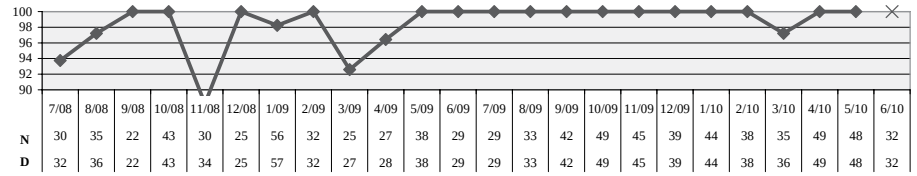
Figure 5

09/10/2010

X = Preliminary Data Only. Actual value may change

Surgical Care Improvement Project (SCIP) - Abx for Knee Procedures

Antibiotic within 1 Hour of Surgical Incision (Percent %)

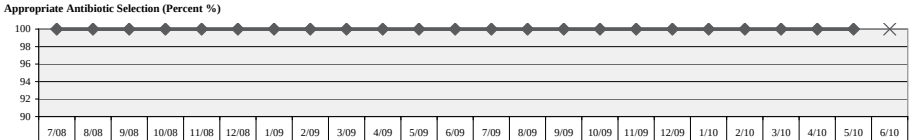


	7/08	8/08	9/08	10/08	11/08	12/08	1/09	2/09	3/09	4/09	5/09	6/09	7/09	8/09	9/09	10/09	11/09	12/09	1/10	2/10	3/10	4/10	5/10	6/10
N	30	35	22	43	30	25	56	32	25	27	38	29	29	33	42	49	45	39	44	38	35	49	48	32
D	32	36	22	43	34	25	57	32	27	28	38	29	29	33	42	49	45	39	44	38	36	49	48	32

Antibiotic discontinued within 24/48 hours Post-op (Percent %)

	7/08	8/08	9/08	10/08	11/08	12/08	1/09	2/09	3/09	4/09	5/09	6/09	7/09	8/09	9/09	10/09	11/09	12/09	1/10	2/10	3/10	4/10	5/10	6/10
N	31	35	21	43	33	25	57	32	27	28	38	29	29	33	40	48	45	37	44	37	36	48	47	32
D	31	36	22	43	34	25	57	32	27	28	38	29	29	33	40	49	45	39	44	37	36	49	48	32

Appropriate Antibiotic Selection (Percent %)



	7/08	8/08	9/08	10/08	11/08	12/08	1/09	2/09	3/09	4/09	5/09	6/09	7/09	8/09	9/09	10/09	11/09	12/09	1/10	2/10	3/10	4/10	5/10	6/10
N	31	37	22	43	34	25	57	32	27	28	38	29	30	33	41	49	45	39	44	38	36	49	48	32
D	31	37	22	43	34	25	57	32	27	28	38	29	30	33	41	49	45	39	44	38	36	49	48	32

N = Numerator (# of visits that pass the indicator) **D = Denominator (# of visits eligible to be evaluated for the indicator)**

Figure 6

Hair removal

Preoperative shaving of the surgical site the night before an operation is associated with a significantly higher SSI risk than other methods of hair removal or no hair removal at all.[62] The increased SSI risk associated with shaving has been attributed to microscopic cuts in the skin that provide a portal of entry for bacteria and a focus for bacterial multiplication. The hair removal methodology should be reviewed with the perioperative staff. The timing of the hair removal and the removal with the use of clippers versus razors are important processes. If hair is removed, it should be as close to the incision as possible. One of the most effective strategies is to remove razors from the OR. In many cases, no hair removal is needed. However, the decision to remove surgical site hair should include consideration of the potential for access to the surgical site and the field of view. Female patients who are undergoing knee replacements, hip replacements or other lower leg surgeries should be instructed not to shave their legs prior to surgery for the reason described above.

Perioperative Normothermia

Several studies specifically address the importance of normothermia in orthopedic surgery. Perioperative hypothermia is physiologically stressful because it elevates blood pressure, heart rate and plasma catecholamine concentration, which may increase the risk of cardiac complications, bleeding, wound infection, and post-anesthesia care unit stay.[63] In the OR, surgical patients are exposed to factors that may alter their thermoregulatory mechanism, leading to postoperative hypothermia. These factors may include cold OR rooms, IV fluids, skin preparations and various forms of anesthesia. One randomized control study of total knee replacements found that forced air warming was more effective than cotton or reflective blankets for preventing hypothermia.[64] Other studies have concluded that active warming is beneficial, does not increase contamination, and decreases the potential for postoperative infections.[65] Studies of the impact of hypothermia on the incidence of wound infection have shown that the hypothermic patient is at an appreciably greater risk for wound infection than a normothermic patient.[66] Intraoperative hypothermia triggers thermoregulatory vasoconstriction, decreasing the partial pressure of oxygen in the tissues, thereby lowering resistance to infection. A reduction in core temperature of 1.9˚C has been shown to triple the incidence of surgical wound infections after colon resection and to increase length of hospital stays.[67] A number of organizations have standing protocols for active warming of patients whose core temperature is at or below 36 degrees Centigrade.

Global Initiatives

The World Health Organization (WHO) has undertaken several initiatives aimed at safe surgical care. International experts around the world convened to review the literature on patient safety and to identify key areas for improvement. One of WHO's major initiatives focused on improved surgical safety by reducing surgical deaths and complications during surgery in four ways:[68]

- by providing information on the role and patterns of surgical safety in public health to clinicians, hospital administrators and public health officials;
- by defining a minimum set of uniform measures, or "surgical vital statistics," for national and international surveillance of surgical care;
- by identifying a simple set of surgical safety standards that are applicable in all countries and settings and are compiled in a checklist for use in operating rooms;
- by initially evaluating and disseminating the checklist and surveillance measures at pilot sites in every WHO region, and then to hospitals worldwide

Preoperative Preparation

Patients who undergo elective surgery should ideally enter the hospital on the day of surgery. Patients who have a prolonged length of stay prior to surgery will be at greater risk for infection due to the likelihood of exposure to infectious organisms, including resistant pathogens, and possible use of invasive devices prior to surgery.

In the preoperative setting, it is important to evaluate patients for medical conditions, encourage them to stop smoking, and instruct them not to shave near the surgical site prior to surgery. Instruction sheets and videos may be useful.

FAQs
(frequently asked questions)
about
"Surgical Site Infections"

What is a Surgical Site Infection (SSI)?

A surgical site infection is an infection that occurs after surgery in the part of the body where the surgery took place. Most patients who have surgery do not develop an infection. However, infections develop in about 1 to 3 out of every 100 patients who have surgery.

Some of the common symptoms of a surgical site infection are:

- Redness and pain around the area where you had surgery
- Drainage of cloudy fluid from your surgical wound
- Fever

Can SSIs be treated?

Yes. Most surgical site infections can be treated with antibiotics. The antibiotic given to you depends on the bacteria (germs) causing the infection. Sometimes patients with SSIs also need another surgery to treat the infection.

What are some of the things that hospitals are doing to prevent SSIs?

To prevent SSIs, doctors, nurses, and other healthcare providers:

- Clean their hands and arms up to their elbows with an antiseptic agent just before the surgery.
- Clean their hands with soap and water or an alcohol-based hand rub before and after caring for each patient.
- May remove some of your hair immediately before your surgery using electric clippers if the hair is in the same area where the procedure will occur. They should not shave you with a razor.
- Wear special hair covers, masks, gowns, and gloves during surgery to keep the surgery area clean.
- Give you antibiotics before your surgery starts. In most cases, you should get antibiotics within 60 minutes before the surgery starts and the antibiotics should be stopped within 24 hours after surgery.
- Clean the skin at the site of your surgery with a special soap that kills germs.

What can I do to help prevent SSIs?

Before your surgery:

- Tell your doctor about other medical problems you may have. Health problems such as allergies, diabetes, and obesity could affect your surgery and your treatment.
- Quit smoking. Patients who smoke get more infections. Talk to your doctor about how you can quit before your surgery.
- Do not shave near where you will have surgery. Shaving with a razor can irritate your skin and make it easier to develop an infection.

At the time of your surgery:

- Speak up if someone tries to shave you with a razor before surgery. Ask why you need to be shaved and talk with your surgeon if you have any concerns.
- Ask if you will get antibiotics before surgery.

After your surgery:

- Make sure that your healthcare providers clean their hands before examining you, either with soap and water or an alcohol-based hand rub.

If you do not see your providers clean their hands, please ask them to do so.

- Family and friends who visit you should not touch the surgical wound or dressings.
- Family and friends should clean their hands with soap and water or an alcohol-based hand rub before and after visiting you. If you do not see them clean their hands, ask them to clean their hands.

What do I need to do when I go home from the hospital?

- Before you go home, your doctor or nurse should explain everything you need to know about taking care of your wound. Make sure you understand how to care for your wound before you leave the hospital.
- Always clean your hands before and after caring for your wound.
- Before you go home, make sure you know who to contact if you have questions or problems after you get home.
- If you have any symptoms of an infection, such as redness and pain at the surgery site, drainage, or fever, call your doctor immediately.

If you have additional questions, please ask your doctor or nurse.

Co-sponsored by:

SHEA IDSA American Hospital Association APIC CDC The Joint Commission

Figure 7

Preoperative Skin Preparation

The goal of preoperative preparation of the patient's skin is to reduce the risk of postoperative SSI by removing soil and transient microorganisms from the skin; reduce the resident microbial count to subpathogenic levels in a short period of time, with the least amount of tissue irritation; and inhibit rapid, rebound growth of microorganisms.

The 1999 Hospital Infection Control Practices Advisory Committee (HICPAC) guidelines for prevention of SSIs recommend that patients be required to shower or bathe with an antiseptic agent at least the night before the operative day.[69, 70]

A systematic review of the evidence for preoperative bathing or showering with antiseptics for prevention of an SSI was conducted.[71] A total of six randomized controlled trials were included in the review. Chlorhexidine gluconate (CHG) 4% solution was compared to a placebo, to unmedicated soap, or to nothing (no wash), administered at various times preoperatively to all types of patients undergoing all types of surgeries. In two studies, washing was performed after hospital admission. In the other four studies, it was not clear if the antiseptic washes were administered at home or in the hospital. Compared to a placebo or soap, washing with CHG did not result in a reduction in SSI. Results were mixed when comparing CHG to no wash. One study found that the CHG wash, when compared to no wash, resulted in a statistically significant reduction in the number of patients with a SSI. Conversely, another study found no difference in the SSI rate between patients who washed with CHG and those who did not wash preoperatively. Finally, in one study, total body washing showed a statistically significant reduction in SSI compared with partial body wash. The authors concluded that there is no clear evidence to support the practice of preoperative showering or bathing with CHG.

Preoperative showering with agents such as CHG has been shown to reduce bacterial colonization of the skin, despite the fact that the evidence is inconclusive as to its link to prevention of SSIs. The act of washing and rinsing removes microorganisms from the skin. Some organisms may be difficult or impossible to kill with the application of CHG alone. *Staphylococcus aureus* is the most common organism causing SSIs and, in 2004, 63% of HAIs were from methicillin-resistant *Staphylococcus aureus*.[72] Many SSIs result from colonization of the surgical site with the patient's own flora, and colonization with *Staphylococcus aureus* is a known risk factor for SSIs.[73] Clinical trials support the use of preoperative antiseptic showers to reduce the number of microorganisms on the skin, including *Staphylococcus aureus*. However, to gain maximum antiseptic effect, it must be allowed to dry completely and not be washed off.[74]

A rinse-free cloth has been introduced as an alternative to CHG showers, and some data suggests ease of use and improved patient compliance as well as reduced rates of SSI.[75] One advantage of the cloth is that CHG is allowed to remain on the skin rather than being washed off. Edminston et al. compared the 2% CHG-impregnated cloth with 4% CHG as topical antiseptic for preparation of the skin prior to surgery, noting greater microbial reductions with the 2% cloth.[76] Further studies are needed to better evaluate the effectiveness of the rinse-free cloth in preventing SSIs.

One strategy to ensure compliance to organizational protocols is a comprehensive tool kit that includes interventions, references, product order information and patient education tools.

See appendix for sample policies

Nasal Decolonization

SSIs continue to be an important complication of orthopedic surgery. *Staphylococcus aureus*, particularly MRSA, remains a significant pathogen in postoperative orthopedic SSIs. A 2000 study that reviewed multiple risk factors

for SSIs following orthopedic surgery identified *Staphylococcus aureus* as the most important and independent risk factor for developing a postoperative infection.[77] An article published in the *New England Journal of Medicine* by Perl and colleagues studied whether preoperative intranasal application of mupirocin ointment would decrease the rate of infections at surgical sites. Results of this randomized control study concluded that use of mupirocin did decrease *Staphylococcus aureus* HAIs but not necessarily SSIs. However, authors suggested that the use of mupirocin was safe and cost-effective for patients with *Staphylococcus aureus* carriage.[78] A recently produced expert guidance document indicated that the role of decolonization therapy to prevent SSIs remains an unresolved issue.[79]

A recent publication by Lee et al. used a computerized model to evaluate the cost-effectiveness of routine preoperative screening and decolonization of orthopedic surgery patients who were colonized with MRSA. They concluded that this routine preoperative screening and decolonization of orthopedic surgery patients may save hospitals and third-party payers money while reducing postoperative infections, even in populations where there is low prevalence of MRSA.[80] A number of organizations report that they routinely screen for MRSA preoperatively and decolonize patients who carry MRSA, using mupirocin nasal ointment. Although organizations may vary in their approaches, it is important that protocols and strategies be standardized. Including these protocols in order sets and pathways is one method of standardization. Most recently Bode and others found that preoperative screening for S. aureus and then cleansing with CHG and intranasal mupirocin were effective in preventing SSI. This investigation did include patients undergoing orthopedic procedures. [see Bode LG, et al. NEJM 2010;362:9-17] One of the concerns with the use of intranasal mupirocin ointment, because it is an antibiotic, is development of resistance. Mupirocin resistance has been documented.[81] Protocols for decolonization in the home or outpatient setting may also be appropriate.

See appendix for sample protocol

The Perioperative Setting

The term "perioperative" encompasses the entire continuum of care for a patient undergoing an elective invasive procedure. While prevention of infection is the goal for all surgical patients, it is a primary concern for orthopedic surgery patients.[82] One of the expected outcomes for surgical intervention is that the patient is free from signs and symptoms of infection, such as pain, foul odor, purulent drainage, and/or fever through 30 days following the procedure.[83] Throughout the patient's perioperative journey, infection prevention requires the application of the principles of microbiology and aseptic practice,[84] as well as effective teamwork.

Preoperative Period

There are several aspects of care that reduce the risk for the development of an SSI in the preoperative period. As noted above, it is important to preoperatively evaluate patients for pre-existing medical conditions. A thorough assessment of the patient's susceptibility and risk factors for infection is a key nursing activity in the preoperative period.This assessment should include identification of the patient's specific risk factors, such as health problems and situations predisposing the patient to infection by: [85]

- identifying pathophysiological risk factors, including, but not limited to, altered gastrointestinal system; anatomic abnormality; autoimmune diseases; blood dyscrasias; chronic diseases; immunodeficiency disorders; impaired circulation; periodontal disease; obesity; sleep deprivation
- identifying treatment-related risk factors, including, but not limited to, chemotherapy; dialysis; medications (i.e., antacids, antibiotics, antifungal agents, antiviral agents, immunosuppressants, steroids); organ transplants; presence of implants; presence of invasive lines; radiation therapy; recent blood transfusions; surgery
- identifying personal and environmental risk factors, such as bites; exposure to contagious agents (healthcare-associated or community-acquired); history of infections; lack of immunizations; personal hygiene factors; malnutrition; moist skin areas; prolonged immobility; smoking; stress; thermal injuries; trauma
- identifying patients at high risk for transmitting HAIs, e.g., persons with antibiotic- or medication-resistant microorganisms, prion diseases, tuberculosis, preoperative colonization of *Staphylococcus aureus*
- identifying maturational risk factors, including but not limited to:
    - newborn: lack of maternal antibodies; lack of normal intestinal flora; open wounds; immature immune system
    - infant or child: lack of immunizations
    - elderly: debilitated, diminished immune response, friable tissues and chronic diseases
- identifying recent history of travel inside or outside the United States
- noting the ASA physical status classification system
- using Spaulding's wound classification system
- determining if the patient is at high risk for infection from endogenous or exogenous sources
- identifying those individuals at high risk for HAIs; a person is considered to be at high risk if he/she has one or more contributing factors or one or more predictors.

Assessment parameters include:

- infection predictors: length and type of procedure; presence of other devices or instruments
- confounding factors: age, nutritional status, health status.

In the ambulatory surgery practice setting, the preoperative nursing assessment is often performed on the day of surgery. Assessments for special populations, such as pediatric patients, older adult patients, high-risk patients, and patients with special needs, may require additional preparation.[86]

Reinforcement of patient education is another vital component in preventing an SSI. When the patient arrives in the preoperative area, a nurse should verify that all preoperative protocols were followed (e.g., preoperative shower or skin cleansing, etc.). Other points to emphasize include questioning the patient as to any skin irritation or hypersensitivity in prior surgical experiences or any new skin conditions, such as boils, eruptions, or rashes.

Hand hygiene, recognized as the single most important method of decreasing HAIs,[87] is a key infection prevention strategy in the preoperative period. Since there are many opportunities for contact in the preoperative setting, organisms that are present on a patient's skin, or shed onto inanimate objects in close proximity to a patient, may be transferred to the hands of caregivers. If hand hygiene is inadequate or omitted entirely, the contaminated hands of the care provider may come in direct contact with another patient. To mitigate the risk of cross contamination, care providers must perform hand antisepsis before and after contact with a patient or objects in close proximity to the patient. If hands are visibly soiled, they should be washed with soap and water for a minimum of 10-15 seconds. The basic principles of antisepsis are especially important, given the volume of orthopedic procedures performed in ambulatory surgery settings where large volumes of patients are often seen in a very short time span.

Intraoperative Period

Skin Antisepsis

Once the patient is placed securely on the OR bed and monitoring devices are applied, the specific type of anesthesia, e.g., general, regional, or monitored anesthesia care (MAC), is administered. The patient is then positioned to accommodate the type of procedure that will be performed. Once the patient is properly positioned, the surgical team then determines the type of skin preparation that will be used. The selection of the preoperative skin antiseptic agent should be based on patient assessment for any allergy or sensitivity to skin preparation agents. The preoperative antiseptic agent should:[88]

- significantly reduce microorganisms on intact skin
- contain a non-irritating antimicrobial preparation
- be broad spectrum and fast acting
- have a persistent effect.

Perioperative personnel must be aware of the clinical considerations regarding the various types of skin antiseptic agents. Some skin preparations that are used include:

- PCMX (has been proven to be minimally effective in the presence of organic matter. The FDA has classified PCMX as a category III; it is still being evaluated.Povidone iodine is an aqueous based prep that is safe and effective in concentrations from 5-10% (0.5-1% available iodine). It has bactericidal activity against gram-positive and gram-negative bacteria. It is also active against mycobacteria, fungi and viruses. Warnings include: avoid "pooling" beneath the patient; prolonged exposure may cause irritation or, rarely, severe skin reactions; and, do not heat prior to application.
- Contraindications in the form of aqueous solutions include irritation and toxicity. If left on the skin for extended periods, it can cause "burning" of tissue.
- Aqueous Chlorhexidine gluconate (CHG) antiseptics are available in 2% or 4% concentrations. CHG exhibits excellent activity against gram-positive and good activity against gram-negative vegetative

organisms and fungi. CHG is also known to have excellent persistent activity.[89] Warnings include avoidance of use on the head or face, the genital area or contact with the meninges.

- Two types of skin preparations available for use appear to have superior efficacy in terms of antimicrobial properties. These include but are not limited to iodophor based compounds with alcohol and Chlorhexidine with alcohol. The results of a randomized, double-blind, placebo-controlled trial published in January 2010 in the *New England Journal of Medicine* in clean-contaminated surgery identified CHG with alcohol as superior to iodoform-based compounds.[90] This study did not compare iodophor based compounds with alcohol to chlorhexidine with alcohol. An observational study published by Swenson, et al. compared the effects of different skin preparation solutions on surgical-site infection rates. An iodine preparation with alcohol was associated with the lowest infection rate. However both the iodine with alcohol and the povidone iodine followed by alcohol were associated with significantly lower infection rates than the CHG in alcohol group.[91]

Two additional observational trials among patients undergoing orthopedic procedures offer additional support for CHG in alcohol.[92, 93] There is also indirect supportive evidence from preparation of skin prior to insertion of central lines that demonstrates CHG-IPA is more effective than povidone iodine in preventing catheter-related bloodstream infection. Still a definitive randomized trial comparing the iodine in alcohol to CHG in alcohol is needed.

- Any skin preparation using alcohol MUST be allowed to dry before beginning surgery due to the flammability of the product. Special care must be taken to allow the prep to dry completely especially before use of electro-surgical equipment.
- The National Quality Forum has recommended use of an antiseptic that contains a combination of CHG or iodine in combination with alcohol in their safe practices for surgery. Conclusions could be drawn that the rapid bactericidal activity of alcohol may be key to successful skin prep and that dual agent skin preps are superior. It is important to note that any product containing alcohol must have a second active ingredient:such as those described above.

Skin flora, particularly *Staphylococcus aureus* and coagulase-negative *Staphylococcus*, are the most common pathogens found in SSIs following orthopedic surgery. Bacteria can enter the wound through the surgical incision. If an implanted prosthesis is present, bacteria can lodge in or near the prosthesis. Because the skin is the easiest access to the wound, adequate skin preparation is a vitally important process.[94]

Surgical Hand Antisepsis

Surgical hand antisepsis, performed before donning sterile gloves, is another important factor in SSI prevention. The purpose of a surgical hand antisepsis is to reduce transient and resident microorganisms on the hands and maintain the bacterial level below baseline, as this may reduce HAIs.[95] In the U.S., a standardized surgical hand scrub or rub should be performed, using either an antimicrobial surgical agent or an alcohol-based antiseptic surgical hand rub with documented persistent and cumulative activity that has met the U.S. FDA regulatory requirements for surgical hand antisepsis. Outside the U.S., products should comply with that jurisdiction's relevant licensing and regulatory authority requirements, which may be different than those of the FDA.

A Cochrane review found alcohol-based rubs to be as effective as aqueous solutions for preventing SSIs in patients.[96] Other investigators reported that the use of scrub brushes had no positive effect on asepsis and may actually increase the risk of infection as a result of skin damage.

Antibiotic Prophylaxis

As part of The Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™, the surgical time-out, performed immediately before starting the invasive procedure or making

the incision, is now a standard of care in surgical settings.[97] Many facilities include antibiotic prophylaxis as a routine part of the time-out. An important consideration in total knee replacements is the infusion of the antibiotic prior to inflation of the tourniquet.

Other Intraoperative Factors

Air Quality

The most common method by which bacteria can gain access into a wound is when the wound is open during the intraoperative period. The quality of air entering the OR should be carefully controlled.[98] Operating room air may contain microbial-laden dust, lint, skin squames, or respiratory droplets.[99] The risk of contamination can be minimized by providing consistent adequate air flow. There are increased numbers of orthopedic cases performed in ambulatory centers which do not operate on a 7 day a week schedule. However, the need to have uninterrupted air flow is vitally important. If airflow is interrupted, rapid air turbulence can stir settled particles, enabling them to become airborne thus increasing the risk for wound contamination.[100] Additional infection prevention measures such as laminar flow in the operating room and body-exhaust surgical suits are other techniques that have been used to prevent infection.[101] Laminar air flow refers to systems that produce little or no turbulence. It is not clear that these measures are essential. As an example, prospective and controlled studies demonstrated a decrease in rates of surgical site infections in total hip and knee prosthesis procedures when laminar airflow technology was used.[102] However, the value and cost-effectiveness of laminar airflow is questionable when surgery occurs in modern facilities that have high rates of air exchange and antimicrobial prophylaxis is given.[103, 104] In a case control study of 26,505 patients undergoing total hip or knee replacement, the infection rate was 1.8 percent and laminar flow ventilation was not a significant factor in reducing infections in a univariate analysis. Computational fluid dynamic (CFD) modeling has been used to assess impact of variations in heating, ventilation and air conditioning (HVAC) parameters on air quality in the OR. This analysis found that vertical, unidirectional, low velocity supply air with returns at various heights in opposite corners was optimal for removal of airborne particulates in an OR. This model has been adopted in the Facility Guideline Institute's Guidelines for Design and Construction of Healthcare Facilities.

Recommendations [ANSI/ASHRAE/ASHE Standard 170: *Ventilation of Health Care Facilities* :

The ceiling in the OR should be monolithic

- air entering the OR should be sequentially filtered through two filters: the first of which should be rated at 30% efficient; the second at 90% efficient.
- The OR should be maintained in positive pressure
- a minimum of 20 air exchanges per hour, with 4 of these from outside air are recommended.
- The airflow should be unidirectional, downwards, with an *average velocity* of the 25 to 35 cfm/ft2 (127 L/s/m2 to 178 L/s/m2) delivered by non-aspirating diffusers. The diffusers should provide an airflow pattern over the patient and surgical team.
- Details on temperature, humidity, etc., are provided in the 2010 FGI Guidelines.
- There should be at least two returns low on sidewalls or at opposite corners with the bottom of these installed approximately 8 in. (203 mm) above the floor.

Double Gloving

The orthopedic literature contains a number of articles on glove use and double gloving. Most experts agree that the addition of a second pair of surgical gloves significantly reduces perforations to innermost gloves and provides a protective barrier to both the patient and surgeon.[105] Therefore, healthcare practitioners should double glove during invasive procedures; a practice supported by AORN, the CDC, the American College of Surgeons, and AAOS.[106]

Traffic Patterns

Studies have also shown that the number of individuals in the operating room and the amount of movement of these individuals within the OR both increase the number of colony-forming units as measured by settle plates within the room.[107] Olsen et al. reported that two or more residents participating in the operative procedure was an independent risk factor for SSIs in spine surgery.[108] Therefore, it is important that movement of personnel is kept to a minimum while invasive procedures are in progress.

Furthermore:[109]

- the doors to the OR should kept closed except during movement of patients, personnel, supplies and equipment, in order to maintain positive pressure; and
- talking and the number of people present in the OR should be minimized during procedures since movement, talking, and uncovered skin areas can contribute to airborne contamination.

Gowns and Drapes

The materials used in gowns and drapes are protective barriers against the transfer of microorganisms, particulates, and fluids to minimize strikethrough and the potential for personnel contamination. Microorganisms can be transferred through barrier materials by wicking of fluids and/or pressure or leaning on a flooded area of the product. Mechanical action such as pressure can result in both liquid and dry penetration of microbes if the pressure exceeds the maximum level of resistance that the material provides.[110] Surgical gowns and drapes should be resistant to tears, punctures, and abrasions. The inability to withstand tears, punctures, and abrasions may allow for passage of microorganisms, particulates, and fluids between sterile and nonsterile areas and expose patients to exogenous organisms.

Bone Cement

Another relevant intraoperative factor in total joint arthroplasty (TJA) is the use of methyl methacrylate, or bone cement. Initially, bone cement was used as a spacer to maintain the joint space and soft-tissue tension for subsequent reconstruction; when antibiotics were added to the cement, they were found to elute into involved tissue area, thus aiding in the eradication of an infection.[111] Antibiotic laden cement (ABLC) was released for commercial distribution in the United States in May 2003, specifically for the treatment and reimplantation of infected arthroplasties. In Europe, Australia and likely other settings, ABLC has been available for many years. The indications and scientific evidence for its use have expanded to primary arthroplasty; however, the use of ABLC for this purpose remains controversial in the United States. Since its release, a variety of cements, cement preparation methods, antibiotics, and doses have been used with varying outcomes. It is important for the OR team to keep in mind that that the current principles of bone cement preparation do not apply in the treatment of infection.

Although the addition of more than 2 g of antibiotic per 40 g of cement reduces the antibiotic's mechanical strength, this is irrelevant to the treatment of infection. Vacuum mixing decreases the cement's porosity, thereby reducing elution of the antibiotic; for this reason, vacuum mixing is contraindicated. Homogeneous, commercial mixing of the antibiotic in cement results in better mechanical strength, but potentially less elution. Using what is considered to be a traditionally poor mixing technique, i.e., "whipping" of the mixture, may actually *improve* elution. Hand mixing, without fully crushing the antibiotic crystals, may also improve elution. Normally, cement is used only in powder form because the liquid reduces mechanical strength. In this application, however, the liquid may increase the elution rate of the antibiotic.

Sterility Assurance

Inadequate sterilization of surgical instruments has resulted in SSI outbreaks.[112] Sterilization processes should be monitored to detect potential failure modes with the goal of improving patient outcomes. A variety of monitoring tools are used to help ensure sterility, such as physical monitors, chemical indicators and biological indicators. These monitoring tools are used to help ensure that instruments and supplies being used on patients are free from microorganisms. Biological indicators have the ability to detect conditions that are not able to kill spores.

The importance of routine inspection of sterile supplies cannot be underestimated. Event-Related Sterility refers to the maintenance of the sterility of packages until they are used. This is based upon the concept that contamination of a sterile item is event-related, and the probability of its occurrence increases over time and with increased handling, storage or environmental conditions. All items should be inspected immediately before being placed on the sterile field and should be visually inspected for proper packaging, processing, package integrity, and inclusion of the sterilizer indicator. If an expiration date is provided, the date should be checked before the package is opened and not used if the item is outdated. The Association for Advancement of Medical Instrumentation (AAMI) has revised the former term "flash sterilization" to immediate use steam sterilization as "the process for steam sterilization of patient care items for immediate use."[113] Although the need for emergency sterilization of any equipment may arise during a surgical case, this process should not be used for convenience or as an alternative to purchasing additional equipment. Flash sterilization is not recommended for implantable equipment such as screws, plates or wires frequently used in orthopedic surgery. Biological indicators (BI) within Process Challenge Devices should be used to monitor every load containing implants. Implants should be quarantined until the results of the BI testing are available.[114]

See Appendix for a sample perioperative nursing care plan.

The Surgical Team: The Importance of Teamwork

In the dynamic and often hectic surgical practice environment, the importance of teamwork as a factor in infection control and prevention must be recognized. There is increasing evidence that teamwork and collaboration are essential to improved patient outcomes. However, because the word "team" has been used so loosely and for so long in healthcare, in many ways it has lost its true meaning. For example, six individuals in a room, each performing his or her own job, can be called a group, but not necessarily a team, since a team is defined by its members' interactions, interdependence, and shared goals.[115]

A team is defined as a group of two or more individuals who must interact and adapt to achieve a common objective.[116] There are two important aspects of the nature of teamwork: the individual's ability to function as a member of the team; and the entire team's ability to function as an efficient collective entity. There are several factors that influence the team's performance, such as task demands, team composition, and the organizational context. Teams must be able to accomplish tasks as a unit, although team members may have individual tasks that change from member to member and from day to day. Consequently, each team member must possess general team competencies and skills that can be transferred from task to task and from team to team. One primary objective in team training is encouraging participation from individual team members, while developing the knowledge and skills necessary to successfully perform as a group member. As a result, team training, involving perioperative staff, surgeons and other members of the surgical team, has become routine in many organizations throughout the country.

In the surgical practice setting, the traditional hierarchical culture has been blamed for the failure of individuals to function as teams in this environment.[117] In this setting, as with all of healthcare, there is a close correlation between communication and safe care.[118] An ethnographic study of OR functioning classified 30% of procedurally

relevant communications between team members as communication failures; more than one-third of these communication failures led immediately to noticeable and potentially dangerous effects on system processes, such as inefficiency, team tension, resource waste, work- around, delay, patient inconvenience, and procedural error.[119] Poor teamwork and communication are latent human failures that must be addressed to achieve an effective safety program within an organization.[120]

Successful surgical intervention depends on interdisciplinary teamwork, which consists of both technical and non-technical skills, defined as follows:[121]

- technical skills consist of knowledge of anatomy, pathology, dexterity, hand-eye coordination, and technical proficiency
- non-technical skills include significant cognitive and interpersonal skills of health care professionals, such as communication, teamwork, leadership, situational awareness, and decision-making.

It has been shown that many of the underlying causes of errors stem from the non-technical aspects of care, rather than a lack of technical expertise. Further, it is stated that improving non-technical skills could reduce the number of errors during surgery, thereby improving patient safety and reducing the risk for SSI.[122]

An example of effective teamwork in the OR is the surgical time-out noted above, which is a key component of The Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery.™ In addition to confirming appropriate antibiotic prophylaxis, for orthopedic surgical patients, it is also important to:

- identify all items that are required for the procedure and use a standardized list to confirm their availability; these items include:[123, 124, 125]
  - relevant documentation (e.g., history and physical, signed procedure consent form, nursing assessment, and pre-anesthesia assessment)
  - labeled diagnostic and radiology test results (e.g., radiology images and scans, or pathology and biopsy reports) that are properly displayed
  - any required blood products, implants, devices, and/or special equipment for the procedure; items that are to be available should be matched to the patient in the procedure area
- agree, at a minimum, on the:
  - correct patient identity
  - correct site, including laterality and the implant to be used (the site should be marked and visible)
  - procedure to be done
  - need to administer antibiotics or fluids for irrigation purposes
  - necessary safety precautions, based on patient history or medication use
- confirm sterility indicators
- identify and address any equipment issues or concerns.

Documentation of the completion of the time-out should include: the correct patient; correct site and side; agreement to procedure; correct patient position; and implants and/or special equipment or special requirements available. See the ASC success story below for an example of teamwork in promoting patient safety related to antibiotic prophylaxis.

Teamwork in Action: An ASC Success Story

A busy ASC developed an effective process for preoperative administration of antibiotics for orthopedic surgery patients in an effort to streamline patient preparation and reduce medication errors as a result of its performance improvement initiatives and SCIP requirements.

In that system, the pharmacy prepares the antibiotic per the physician's order. Upon admission to the pre-op holding area, the RN verifies the patient's allergies and the physician order, and then tapes the prepared antibiotic to the IV solution bag. The CRNA then administers the antibiotic when the patient is being transported to the OR. This process allows the antibiotic to be administrated within one hour prior to the incision. During the pre-procedure time-out, the OR team – RN, CRNA, and surgeon – ask if the antibiotic has been administered. Antibiotic administration is then documented in the electronic record. If the patient requires vancomycin, the preadmission testing RN calls the patient to request that he/she arrive two hours prior to the scheduled surgery time to allow adequate time for administration of the antibiotic.

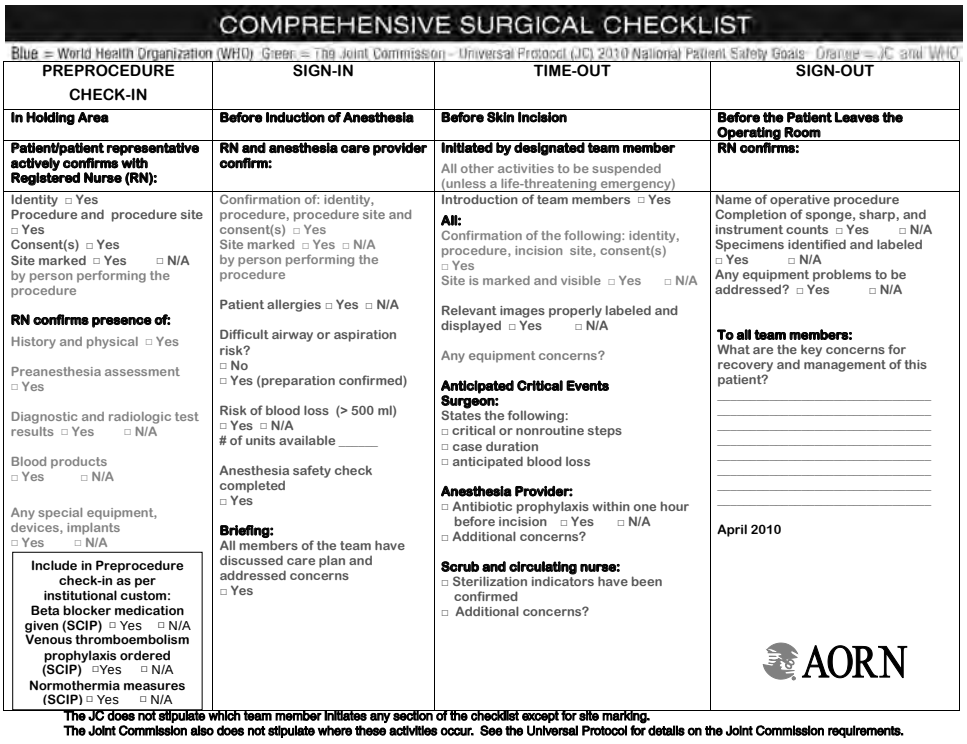
Example provided by Donna Bowers, RN, Executive Director Asheville Surgery Center, Asheville,

Teamwork in Action: An Inpatient Success Story

The infection prevention team, in collaboration with surgeons, nursing and perioperative staff, developed a comprehensive approach towards reduction of SSIs on the orthopedic service. Noting that more than 50% of the orthopedic SSIs were caused by MRSA, and that overall rates of SSI in total joint replacements were higher than the NHSN mean, a comprehensive orthopedic infection elimination program was instituted. This program consisted of skin preparation with CHG cloths the night before and morning of surgery, preoperative screening for MRSA colonization, addition of intravenous vancomycin prophylaxis to the standard antibiotic prophylaxis protocol for identified carriers, and administration of intranasal mupirocin ointment to all patients, regardless of colonization status for five days, beginning the day before surgery. This comprehensive approach required extensive teamwork and collaboration. Preoperative prophylaxis protocols and mupirocin decolonization therapy was added to order sets and pathways. Surgeons, perioperative and postoperative staff received extensive education. To showcase progress and motivate staff, results were displayed prominently on the post-op unit. The service has not had a MRSA SSI in a year, and overall SSI rates on orthopedics decreased by 60%.

Example provided by Michelle Vignari, RN, CIC, Rochester General Hospital, Rochester,

Checklists, which can be customized by each facility, have also been developed to assist the perioperative team in conducting and documenting the surgical time-out. See below for a sample checklist developed by AORN.



COMPREHENSIVE SURGICAL CHECKLIST

Blue = World Health Organization (WHO) Green = The Joint Commission – Universal Protocol (JC) 2010 National Patient Safety Goals Orange = JC and WHO

PREPROCEDURE CHECK-IN	SIGN-IN	TIME-OUT	SIGN-OUT
In Holding Area	**Before Induction of Anesthesia**	**Before Skin Incision**	**Before the Patient Leaves the Operating Room**
Patient/patient representative actively confirms with Registered Nurse (RN):	**RN and anesthesia care provider confirm:**	**Initiated by designated team member** All other activities to be suspended (unless a life-threatening emergency)	**RN confirms:**
Identity □ Yes Procedure and procedure site □ Yes Consent(s) □ Yes Site marked □ Yes □ N/A by person performing the procedure **RN confirms presence of:** History and physical □ Yes Preanesthesia assessment □ Yes Diagnostic and radiologic test results □ Yes □ N/A Blood products □ Yes □ N/A Any special equipment, devices, implants □ Yes □ N/A **Include in Preprocedure check-in as per institutional custom:** **Beta blocker medication given (SCIP)** □ Yes □ N/A **Venous thromboembolism prophylaxis ordered (SCIP)** □Yes □ N/A **Normothermia measures (SCIP)** □ Yes □ N/A	Confirmation of: identity, procedure, procedure site and consent(s) □ Yes Site marked □ Yes □ N/A by person performing the procedure Patient allergies □ Yes □ N/A Difficult airway or aspiration risk? □ No □ Yes (preparation confirmed) Risk of blood loss (> 500 ml) □ Yes □ N/A # of units available _____ Anesthesia safety check completed □ Yes **Briefing:** All members of the team have discussed care plan and addressed concerns □ Yes	Introduction of team members □ Yes **All:** Confirmation of the following: identity, procedure, incision site, consent(s) □ Yes Site is marked and visible □ Yes □ N/A Relevant images properly labeled and displayed □ Yes □ N/A Any equipment concerns? **Anticipated Critical Events** **Surgeon:** States the following: □ critical or nonroutine steps □ case duration □ anticipated blood loss **Anesthesia Provider:** □ Antibiotic prophylaxis within one hour before incision □ Yes □ N/A □ Additional concerns? **Scrub and circulating nurse:** □ Sterilization indicators have been confirmed □ Additional concerns?	Name of operative procedure Completion of sponge, sharp, and instrument counts □ Yes □ N/A Specimens identified and labeled □ Yes □ N/A Any equipment problems to be addressed? □ Yes □ N/A **To all team members:** What are the key concerns for recovery and management of this patient? _____ _____ _____ _____ _____ _____ _____ _____ April 2010 AORN

The JC does not stipulate which team member initiates any section of the checklist except for site marking.
The Joint Commission also does not stipulate where these activities occur. See the Universal Protocol for details on the Joint Commission requirements.

Figure 8

The Universal Protocol is implemented most successfully in facilities with a culture that promotes teamwork and where all individuals feel empowered to protect patient safety.[126] A just culture is an environment where actions are analyzed to ensure that individual accountability is established and appropriate actions are taken; such a culture will provide an atmosphere where perioperative team members can openly discuss patient safety or infection control issues, such as errors or system issues, without fear of reprisal.[127, 128] Because analyzing medical errors is an integral part of improving patient safety, analytical methods are ineffective if team members are bound by a "code of silence" or are fearful of retribution. Creating a just culture promotes both professional accountability and reporting of medical errors by fostering a professional milieu that includes reporting systems and processes for improving patient safety through organized analysis.

Patient hand-off is also an important aspect of care related to infection prevention and communication in the perioperative setting. Patient hand-off is defined as the point at which a patient is transferred, either physically to a different part of the healthcare facility or administratively when a new member of the care team takes responsibility; this is a period of high risk to the patient, because the hand-offs usually occur in a chaotic environment.[129] The surgical patient is more susceptible to hand-off errors because of the numerous checkpoints and transitions that occur throughout the patient's perioperative journey, e.g. shift change or break relief; report to the post-anesthesia care unit (PACU) nurse; hand-off to the inpatient unit.[130] The failures in communication and teamwork associated with hand-offs may be among the most important contributors to preventable adverse events in healthcare. Initiatives are underway in many organizations to improve communication within and between healthcare teams to ensure that patient care information is communicated consistently during all patient hand-offs and other patient care transitions. For example, pertinent information related to the patient's medical history, allergies, the operative procedure, and administration of antibiotic therapy throughout all phases of perioperative care must be communicated accurately at all patient hand-offs in order to reduce the risk for SSI and adverse effects.

Another essential aspect of teamwork in the care of the orthopedic surgery patient is effective collaboration between the perioperative nurse and the IP. Both of these professionals possess knowledge of surgical procedures and infection prevention protocols, including literature findings and practice guidelines; additionally, they both have a broad range of communication and leadership skills (see Table Y).[131] Today, successful utilization of these skills requires an evolving set of new skills due to the change in reporting structures, treatment practices, job responsibilities, and work force composition. For example, as noted above, the traditional hierarchical culture, i.e., the flow of power and authority from the "top down," is being replaced by horizontal, lateral interactions among staff members with equal power and authority. As a result, both perioperative nurses and IPs may find that they need to influence the behavior of other team members over whom they have no direct authority. These new roles encourage interdepartmental teamwork by sharing information about safety, for the wellbeing of both patients and coworkers.

Table Y: Comparison of Expertise of the Perioperative Nurse and IP

Perioperative Nurse	IP
• Clinical expertise; in-depth knowledge of perioperative clinical needs • Knowledge of findings in nursing and perioperative literature • A patient care focus: both patient safety and infection prevention • Ability to prioritize patient needs, surgeon preferences, costs • Representation to achieve consensus within the surgical team • A "surgical conscience" • Knowledge of regulations and compliance in perioperative areas identified by the state health department, The Joint Commission, and CMS	• Clinical expertise on infection risk, control, and prevention • Knowledge of findings in infection control and prevention literature • Experience of compliance with policies, procedures, and accepted practices • A focus on patient and healthcare worker safety; identifying infection safety risks both to patients and staff members, with an emphasis on control and prevention • An understanding of compliance with regulations set forth by OSHA, U.S. FDA, and CDC • Ability to apply national guidelines in a cost-effective manner • A "facility conscience"

This collaboration is particularly relevant in the selection, use, and standardization of products and medical devices. The goals of product standardization and value analysis processes are to select functional and reliable products that are safe, cost-effective, and promote quality care. A multidisciplinary committee, with representation by IPs, should be assembled in order to select the most appropriate products and medical devices.[132] Together, perioperative nurses and IPs not only offer leadership in product evaluation, selection, and introduction into clinical practice, they can also integrate this process into established practices based on standards of safety and quality of patient care. Ultimately, this results in the incorporation of new products and technology efficiently and correctly, without compromising the quality of patient care.[133]

Collaboration between perioperative personnel and IPs is also valuable in the ambulatory surgery setting. As previously noted, in the U.S., additional work by the HHS will include ASCs as part of the Tier Two Action Plan to prevent HAIs.[134] The new infection prevention and controlrequirements set forth by CMS will help to ensure that ASCs develop infection prevention policies based upon nationally recognized guidelines and that the policies are under the direction of a professional trained in infection control.

However, the ultimate accountability for HAI prevention and safe care rests with the ASC itself. ASCs need to proactively embrace a culture of safety and make staff allocation of resources and education for HAI risk reduction

a priority. Understanding where and in what ways the risks and hazards associated with infections are embedded in the process and structure of care within ASCs is vital to the development of safe practices for HAI prevention. Moreover, ASCs may benefit from regular access to an individual trained or certified in infection prevention, who could provide more customized education for the staff and therefore meet the specific needs of the facility better than the more generalized information provided by non-customized educational sessions on infection prevention and control.

Postoperative Period

Upon completion of the procedure, a sterile dressing is applied to the wound and secured with tape, based on patient characteristics such as skin condition, allergies, amount of strength and elasticity required, and anticipated frequency of dressing changes.[135] For wounds that are primarily closed, the sterile dressing should remain in place for 24-48 hours postoperatively. There is some debate over occlusive versus absorptive dressings. Hutchinson and McGuckin reviewed 111 studies and found that the rate of infection under occlusive dressing was lower than under non-occlusive dressings (2.6% compared with 7.1%)[136] A 2003 review of dressings recommended three layers: a non-adhering layer, an absorptive layer and an occlusive dressing.[137]

In the PACU, all surgical dressings should be checked for drainage and closure.[138] The PACU nurse should measure the patient's temperature upon admission and apply active warming measures, such as forced-air warming, until the patient reaches a temperature of ≥36˚C. Because patients undergoing orthopedic surgery can suffer dire consequences from an infection, strict asepsis in changing dressing and handling drains is required. If drains are present to minimize blood accumulation and the potential for infection, care must be taken to ensure that these drains maintain suction. The characteristics of wound drainage, e.g., type, consistency, amount, and color should be observed and evaluated for signs of infection; additional PACU interventions include:[139]

- assess the wound if the patient has signs or symptoms of infection, such as a fever, unusual wound pain, redness and heat at the wound site, or edema
- examine and compare the characteristics of the incision regularly, observing for well-approximated incision edges and signs of infection (e.g. heat, redness, swelling, unusual pain, odor), dehiscence, or evisceration.

The PACU nurse should also assess the patient for the development of compartment syndrome as an infection prevention measure. Compartment syndrome develops when swelling or bleeding occurs within a compartment, i.e., the fascial sheath that encloses bone, muscle, nerves, blood vessels and soft tissue.[140, 141] Because the fascia does not stretch, the increased pressure placed on the capillaries, nerves, and muscles in the compartment causes circulatory compromise, which leads to diminished function of the limb and tissue necrosis. The two primary causes of increased pressure in the compartment are constriction from the outside, such as a cast or bandage that reduces the size of the compartment; or increased pressure from within the compartment, e.g., swelling. The characteristic symptoms of compartment syndrome are intense pain that is unrelieved by conventional methods, paresthesia, and sharp pain on passive stretching of the middle finger of the affected arm or the large toe of the affected leg. Progressive symptoms include decreased strength, sensation, and capillary refilling; peripheral pulses are not usually compromised. In order to prevent tissue damage and reduce the risk for infection, a nurse must intervene immediately by elevating the extremity, applying ice, and releasing the restrictive dressing.

At the time of discharge, written postoperative and follow-up care instructions should be provided to the patient. These instructions should reflect the patient's individual informational needs specific to home care, response to unexpected events, and physician follow-up.[142] It is important that the patient be compliant with postoperative instructions. The patient must watch for signs and symptoms of infection after surgery that include, but are not limited to, fever, malaise, erythema of incision site, and drainage from incision site. Comorbidities that are detrimental to healing include, but are not limited to, obesity, immunosuppression, use of steroids, chronic illness, diabetes, and advanced age.

Summary of Key Points[143,144]

Key Point	Recommendation
Vertical, Unidirectional Flow at low velocity over the OR table	A minimum of 20 air changes/hour
Body Evacuation Suits	Generally recommended for total joint arthroplasty
Surgical Hand Antisepsis	Use either an antimicrobial surgical scrub agent or an alcohol-based surgical hand rub with documented cumulative and persistent activity. Use of alcohol product immediately reduces resident flora by 95% and continues to act for hours
Hair Removal	Hair removal: either no hair removal or removal with clippers immediately before surgery; razors are not appropriate and are associated with an SSI rate of 3.1%-20%
Skin Prep	Preoperative skin cleansing (CHG) Surgical prep Use a dual agent with alcohol and active ingredient (CHG, iodine povacrylex, povodine iodine) Allow prep to dry completely Avoid pooling of the prep.
Drains	Controlled studies show no benefit Meta-analysis: shows increased transfusions and no benefit in total knee or hip
Antibiotic Cement	Norwegian Arthroplasty Register 2006: evidence of effectiveness; now widely used in primary surgery in Europe FDA-approved in the U.S. for revision surgery
Traffic Control	Multiple studies support limiting the number of and movement of OR personnel
Maintenance of Body Temperature	Active warming of patients whose core temperature is at or below 36 degrees C
Universal Protocol/Time-Out	Identify all items required for the procedure: • relevant documentation • labeled diagnostic and radiology test results are properly displayed • any required blood products, implants, devices, and/or special equipment for the procedure; match the items to the patient in the procedure area • use a standardized list to confirm availability Agree on the: • correct patient identity • correct site (site is marked and visible) • procedure to be done Confirm sterility indicators Identify and address any equipment issues or concerns Document the time-out

Future Trends

Although the use of antimicrobial sutures is not a routine practice, the benefits are becoming increasingly apparent. Recent evidence-based clinical studies have demonstrated both the clinical and economic benefit of this technology.[145] Future studies may prove useful. Likewise, advances in antimicrobial coatings for products such as implants, instruments, equipment and the environment may provide additional support to reach the goal of zero SSIs.[146] The practice of prescreening selected patients for MRSA prior to surgery is controversial. However, future trends could incorporate this as a recommended practice, as part of a comprehensive program to eliminate SSIs in orthopedic surgery, especially in cases involving an implantable device. Future trends in preoperative preparation will likely include standardized protocols for preoperative showers and state-of-the-art skin cleansing, which will become the recommended standard of practice. Innovative techniques for postoperative care, including optimal dressing materials and techniques, will most likely become the standard of care.

Targeting Zero

As healthcare has attempted to move from silos of care driven by specialized groups to collaborative groups and integrated systems, it is imperative that both processes and products are designed and implemented in the most effective and efficient manner to achieve desired outcomes. Central to this theme is the philosophy of targeting zero. Targeting Zero is the philosophy that every healthcare institution should be working toward a goal of zero HAIs. While not all HAIs are preventable, APIC believes that all organizations should set the aspirational goal of elimination and strive for zero infections. Every HAI impacts the life of a patient and a family, and even one HAI should be considered too many.

To improve our results, it is important to collaborate with all stakeholders in the development of a culture that holds each other accountable for adhering to proven infection prevention measures and practices. Essential components include a focus on patient-centered care, an engaged and committed leadership, teamwork and communication. Several organizations critically evaluate each individual event to identify gaps and opportunities in developing and fostering a culture that even one infection is “one too many.”

(A sample critical event analysis is included in the Appendix.)

LESSONS LEARNED

- In today's surgical practice environment, challenged by newly recognized pathogens and well-known pathogens that have become resistant to current therapeutic modalities, all members of the healthcare team must remain aware of the impact of HAIs in orthopedic surgical patients and must implement evidence-based prevention strategies to reduce the incidence of HAIs.
- Given the associated unnecessary morbidity and mortality that could be prevented, the suffering that could be eliminated, and the money that could be saved, no healthcare organization can risk ignoring the benefits of effective strategies aimed at preventing HAIs.
- Effective teamwork and communication among all members of the surgical team is an important factor in improving patient outcomes.
- Various tools and checklists, which can be customized by the facility, have been developed to assist in preventing SSIs in orthopedic surgical patients.
- Perioperative personnel and IPs are in a unique position to provide leadership in improving the quality and safety of patient care; by forming an alliance, they can be effective change agents in product evaluation and selection, thereby promoting positive patient outcomes.

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Appendices

Infection Control and Prevention
Surgical Services Audit Checklist

Patient Name: _____ MRN #: _____ Admit date: _____

Surgery Date: _____ Day of week: _____

Scheduled Time: _____ First case/Last case/Other (circle one)

OR Pavilion: _____ OR Room: _____ Surgeon: _____

Scheduled Procedure: _____ Emergent Case: Y/N

Actual Procedure: _____

IC Time in: _____ IC Time out: _____ Total minutes of observation: _____

Time of incision: _____ Time of closure: _____ Duration of case: _____

Case #:
Patients initials:
Observer initials:

Intraoperative Observation	Performed Y/N/ND	Detail	Instructions and Comments
Environment—Environmental Services observed cleaning between cases			
Environment—room has been terminally cleaned			For first case only
Environment – General Cleanliness			
Environment – Equipment Clean			Anesthesia equipment, cords, lights
Environment – Room temperature/ humidity		_____F° _____C° Relative humidity _____% Time observed: _____	
Environment – Ventilation			Confirm appropriate pressure settings
Pre-Op Skin Prep—Hair removal		Performed prior to OR or Performed in the OR or NA	Circle one
Pre-Op Skin Prep—Hair removal method		Clipper Razor Depilatory cream	Circle one

Case #:
Patients initials:
Observer initials:

Intraoperative Observation	**Performed Y/N/ND**	**Detail**	**Instructions and Comments**
Pre-Op Skin Prep		Product Used: Detail Procedure:	
OR Personnel—number present	Surgeon: Resident: Medical Student: Anesthesia: Circulating RN: Scrub RN/Tech: Vendor: Other: Unknown: Total:		Tick mark for each individual present during observation
Scrub Procedure—role of personnel observed		#1: #2: #3:	
Scrub Procedure—nail pick used		#1: #2: #3:	If first case
Scrub Procedure—hand wash		#1: #2: #3:	

Case #:
Patients initials:
Observer initials:

Intraoperative Observation	Performed Y/N/ND	Detail	Instructions and Comments
Scrub Procedure—products used		#1: Avaguard Brush Brush Type: #2: Avaguard Brush Brush Type: #3: Avaguard Brush Brush Type:	Brushes by color: • Ultradex (blue package) • Povidone Iodine (brown package) • Detergent Free (green package)
Scrub Procedure—technique		#1: Correct sequence: Y/N Correct duration: Y/N #2: Correct sequence: Y/N Correct duration: Y/N #3: Correct sequence: Y/N Correct duration: Y/N	
Sterile Tray Set Up		Integrity of wrapping: Indicator Check: Integrator Check:	
Sterile Tray—closing tray for dirty cases			
Sterile Field Maintained			
Environment—Frequency of door opening		Door to core: Door to semi-restricted corridor: Door to substerile:	Tick mark for each door opening
Time Out Performed		Y/N	Circle one
Surgical attire—cap/hood		Worn by all present? Y/N Appropriate use? Y/N Removed at end of procedure? Y/N/not observed	
Surgical attire—mask		Worn by all present? Y/N Appropriate use? Y/N Removed at end of procedure? Y/N/not observed	
Surgical attire—gown		Worn by all present? Y/N Appropriate use? Y/N Removed at end of procedure? Y/N/not observed	
Surgical attire—safety shields		Worn by all present? Y/N Appropriate use? Y/N Removed at end of procedure? Y/N/not observed	
Surgical attire—shoe covers		Worn by all present? Y/N Appropriate use? Y/N Removed at end of procedure? Y/N/not observed	

Case #:
Patients initials:
Observer initials:

Intraoperative Observation	**Performed Y/N/ND**	**Detail**	**Instructions and Comments**
Surgical attire—gloves		Appropriate use? Y/N Changed with tears? Y/N Removed at end of procedure? Y/N/not observed	
Surgical attire—gloves changed for dirty cases			Change before closing?
Surgical attire—name badges			
Surgical attire—jewelry		Rings removed? Y/N? Other jewelry removed or totally confined under attire? Y/N Comments:	Other jewelry – watches, earrings, bracelets, necklaces
Surgical attire--fingernails		Excess fingernail length? Y/N/ND Comments: Artificial nails: Y/N/ND Comments:	Excess=greater than ¼ inch.
Flash Performed		Reason and Item/s Flashed:	
Pt Temp		Temp monitoring?: Y/N/ND Warming Performed? Y/N/ND Location (geographic): Location (anatomic): Method:	
General Observations			

Case #:
Patients initials:
Observer initials:

Retrospective Review	Performed Y/N/ ND	Detail	Comments
Wound class—recorded in Surginet			
Wound class—IC assessment			If different than above
ASA score			
Pre-op Antiseptic showering			
Pre-op nares cultures (for sternotomies)			
Peri-op mupirocin (for sternotomies)			
Pre-op oral decontamination (for colorectal surgery only)		Agent used: Times administered: Time of incision: Meets guidelines: Y/N	1 g of neomycin plus 1 g of erythromycin at 1 PM, 2 PM and 11 PM **OR** 2 g of neomycin plus 2 g of metronidazole at 7 PM and 11 PM the day before an 8 AM operation
Antimicrobial Prophylaxis—timing		Time of infusion: Time of incision: Meets guidelines? Y/N	Cefazolin/Ancef: 0-60 min. prior to incision. Vanco/fluoroquinolone: 60-120 min. prior to incision.
Antimicrobial Prophylaxis—choice		Agent used: Allergies: Consistent with NMH guidelines?: Y/N	
Antimicrobial Prophylaxis—redose		Was a second dose of cefazolin administered for cases > 4 hours? Y/N	
Estimated blood loss			
# Units PRBC			If transfused
Intraoperative—euglycemia (for cardiac surgery)			
Intraoperative—Drains placed		Y/N	
Intraoperative—Drains placed		# of drains: Type of drains:	
Post-operative—Timing of drain removal		POD:	

Guideline to Attempt Decolonization from MRSA

Published studies have shown below procedures often effective. Guidance from large scale clinical trials is not available. In response to increasing MRSA, both from the community (CA-MRSA) as well as health care associated MRSA, below consensus recommendations have been created.

Experienced clinicians may vary in their treatment approach

Basic principles of therapy:

- *Staph aureus* is a very common organism. We all are exposed.
- Colonization of the nose, and subsequently on the skin, is frequent. Approximately 60% of people are intermittently colonized, 20% always colonized, 20% never.
- Colonization with a certain strain of bacteria can persist for years.
- Spread between people is by skin contact (shaking hands, etc.) and sometimes on equipment (eg. hospital bedrail, gym workout equipment, home utensils, cups, TV remote, computer keyboards, stethoscopes).

Decolonization procedure:

1. **All active skin infection sites must be resolved before decolonization becomes feasible.** Boils must be drained. Antibiotics may be needed. Soaks or warm compresses are appropriate.
2. **Ideally, no chronic intravenous device is present** (e.g. Hickman, PICC line, etc.), and urinary catheters should be avoided.
3. **Colonization eradication should be attempted at home,** not in the hospital.
4. **Chlorhexidine or hexachlorophene antiseptic soap:**
   - Wash whole body (from scalp to toes) once daily. A big lather is not necessary! Skin moisturizer may be applied for dry skin after bathing.
   - Remove all artificial nails and all fingernail polish.
   - Scrub fingernails for one minute with nail brush twice daily.
   - **Duration: 7 days**
5. **Mupirocin 2% ointment**
   - Apply inside each nostril twice daily for 7 days, using a cotton tipped swab. No need to put deep into the nose. One Rx enough for all.
   - **Duration: 7 days**
6. **Oral antibiotics:**
   - Are not required for decolonization
   - May be used to decrease gastrointestinal colonization, and may include clindamycin, doxycycline, or TMP-SMZ, occasionally with rifampin
7. **Encourage treatment of all household members (and regular sexual contacts) with chlorhexidine/ hexachlorophene and mupirocin during the same time period.**
8. Post-treatment nasal culture for surveillance is optional and not encouraged.

Patient Information for Decolonization (trying to get rid) of MRSA (a strain of staphylococcus "staph" aureus)

Approved by Chiefs of Infectious Disease and Dermatology, August 2006

MRSA, a resistant staph bacteria, is causing more infections throughout the country, often not associated with hospitals or health care. This strain, as well as hospital strains of MRSA, spread easily from person to person.

- **They may look like spider bites, but probably are not.**
- Anyone can get this new strain, it does not mean you were not keeping clean.
- Some people may be colonized without having symptoms.

Basic principles of therapy:

- ***Staph aureus* is a very common organism. We all are exposed.**
- Colonization of the nose, and subsequently on the skin, is frequent. Approximately 60% of people are intermittently colonized, 20% always colonized, 20% never.
- **Everyone should wash their hands after touching their nose or face.**
- Colonization with a certain strain of bacteria can persist for years.
- **Spread between people is by skin contact** (shaking hands, etc.) and sometimes on equipment (eg. hospital bedrail, gym workout equipment, home utensils, cups, TV remote, computer keyboards, door knobs, stethoscopes)
- Infection **may** continue to recur until the new strain is removed from your body, and for that decolonization has been recommended to you. Please follow the steps below.

Decolonization procedure:

All active skin infection sites must be resolved before decolonization becomes feasible. Boils must be drained. Antibiotics may be needed. Soaks or warm compresses are appropriate.

Colonization eradication should be attempted at home, not in the hospital.

Chlorhexidine or hexachlorophene antiseptic soap:

- Wash whole body (from scalp to toes) once daily. A big lather is not necessary! Apply skin moisturizer for dry skin after bathing.
- Remove all artificial nails and all fingernail polish.
- Scrub fingernails for one minute with nail brush twice daily.
- Pay special attention to washing your armpits, groin, and by your rectum. Dry with a clean towel, and always put on clean clothes. Change bed sheets frequently**.**
- **Duration: 7 days**

Mupirocin 2% ointment

- Apply inside each nostril twice daily for 7 days, using a cotton tipped swab. No need to put deep into the nose. One Rx enough for all.
- **Duration: 7 days**

Oral antibiotics are not required for decolonization, but may be used in some settings.

Household members (and regular sexual partners) should be treated with chlorhexidine or hexachlorophen and mupirocin during the same time period (because they may be asymptomatic carriers; this is safe for children)**.**

SURGICAL SITE INFECTION (SSI) PREVENTION:

IHI How To Guide: http://www.IHI SSI Prevention How To Guide

1. Appropriate use of antibiotics
2. Appropriate use of prophylactic antibiotics
3. Appropriate hair removal

ADDITIONAL OR "PLUS" MEASURES TO OPTIMIZE INFECTION RISK REDUCTION:

Intervention	References	Product Order Info	Tools
Chlorhexidine (CHG): 1. Skin Prep: Chlorhexidine/alcohol 2. Pre-op antiseptic bathing 3. Pre-op CHG oral rinse night before and morning of surgery to reduce the risk of post op pneumonia for those to receive general anesthesia 4. Post op antiseptic bathing	1. C:\Documents and Settings\DNSSAB\My 2. C:\Documents and Settings\DNSSAB\My C:\Documents and Settings\DNSSAB\My C:\Documents and Settings\DNSSAB\My C:\Documents and Settings\DNSSAB\My 3. C:\Documents and Settings\DNSSAB\My 4. C:\Documents and Settings\DNSSAB\My 5. C:\Documents and Settings\DNSSAB\My	Skin Prep: Order Number CHG impregnated wash cloths: CHG oral rinse (pre op)	Pt instructions: Kaiser Sunnyside Preop Skin Prep Patient Teaching **4 min video:** pre/ post op CHG cloths, oral rinse, oral care:
5. OR traffic control	C:\Documents and Settings\DNSSAB\My	**N/A**	**Traffic counters:** C:\Documents and Settings\DNSSAB\My

SSI Prevention continued:

Intervention	References	Product Order Info	Tools
6. Hair removal: • Avoid if possible • By clipper instead of razor immediately before surgery (in pre op **not** OR) • Sterilization of clipper hand piece between cases • Removal clipped hair from skin • Patient teaching: e.g. ensure female patients do not shave legs one week before total knee replacement	C:\Documents and Settings\DNSSAB\My	• Clipper kit • clipper blades blade for sensitive skin	**Patient education:** Kaiser Sunnyside Patient Teaching SSI First do do harm patient info: http://www.SSI Prevention education Safe Care patient info: http://www.safe care campaign

Intervention	References	Product Order Info	Tools
7. Formal observations in OR looking for infection prevention related issues	Bardowski L et al "Direct observation in the OR: First step to best practice" APIC conference June 2009 #18-201	N/A	C:\Documents and Settings\DNSSAB\My C:\Documents and Settings\DNSSAB\My
8. Ensure for ortho cases that pre op antibiotic is infused 20 minutes prior to tourniquette application.			
9. Antiseptic dressings post op	C:\Documents and Settings\DNSSAB\My C:\Documents and Settings\DNSSAB\My C:\Documents and Settings\DNSSAB\My		N/A
10. Decolonization - MRSA prior to high risk procedures; schedule MRSA+ infected patients at end of day if possible	C:\Documents and Settings\DNSSAB\My C:\Documents and Settings\DNSSAB\My		C:\Documents and Settings\DNSSAB\My
11. Glucose level: minimizing the extremes of glucose during perioperative care	C:\Documents and Settings\DNSSAB\My C:\Documents and Settings\DNSSAB\My		N/A
12. Normothermia other than colon procedures	C:\Documents and Settings\DNSSAB\My		N/A
13. Covering implants/grafts on OR table with sterile, non-linting towel if unwrapped ahead of time.	C:\Documents and Settings\DNSSAB\My		N/A
14. Change surgical mask between cases/breaks (after 90 minutes can measure nasopharyngeal shedding).	Recommended by one content expert: Charles Edmiston, PhD: **cedmisto@mcw.edu**		N/A
15. Routine schedule for ultrasonic scrubbing/cleaning of OR equipment including tables, guerneys and IV poles.			
16. Routine ventilation check to ensure HEPA filters changed per schedule and OR rooms are positive pressure minimum of 15 ACH/hr			

2010 OR OBSERVATION CHECKLIST for Assessment of Infection Prevention Efforts

Date of observation: _____ **Time: from** _____ **to** _____ **OR#** _____ **Observer:** _____
Procedure(s): _____

OR/PATIENT STANDARDS	Compliant: YES	Compliant: NO	NA	DESCRIPTION/COMMENTS
OR Environment:				
OR appears clean, dust free, uncluttered				
OR facility in good repair e.g. no holes in walls, floors or ceiling				
Solid ceiling – no tiles				
Interim (between cases) environmental cleaning performed – directionally from top to bottom				
Doors closed, traffic in and out of room kept to minimum during case				# door openings/hour
Number personnel in room kept to a minimum				# personnel in room during case
Perioperative Patient Care:				
Pre-op antibiotic given by anesthesia personnel within 60 minutes prior to incision				
IV injection ports swabbed prior to access				
Hair removal: performed **before** entering OR room (planned hair removal - occasionally additional hair must be clipped or done in the OR)				
Pre-op skin prep: ⇨ Dual agent prep used (Chloraprep or Duraprep)				Name antiseptic
⇨ Application technique (from center out)				Describe application method
Attire: (for any person entering semirestricted and restricted areas of surgical suite)				
Properly tied surgical masks				
Surgical caps/hood cover **all** head hair				
Chest and beard hair fully covered				
For all staff, no artificial nails, natural nails short				
Dress code followed				
⇨ No rings. Other jewelry (watches, earrings, bracelets, necklaces, piercing) should be removed or totally confined within scrub attire				
⇨ No fanny packs				
⇨ All wear long sleeves (approved cover jacket)				
⇨ No turtlenecks				
⇨ Shirts tucked				
⇨ No fleece				
Sterile Field:				
Sterile items left open no > than 60 minutes prior to patient entering room and should be constantly monitored during that time period				

OR Observation Checklist
Developed by KP Periop/IC based on a tool shared by Gwenda Felizardo, RN, BSN, CIC, Group Health Cooperative, Tacoma, Washington

OR/PATIENTS STANDARDS	Compliant YES	Compliant NO	N/A	DESCRIPTION/ COMMENTS
Scrubbed persons maintain sterility of sterile gown, gloves, supplies				
Hands remain above waist				
Items introduced into sterile field opened, dispensed, transferred by methods to maintain sterility/integrity				
Items/devices dropped below level of the OR table are considered contaminated				
Surgical equipment (e.g. cables, tubing) should be secured to sterile field with non-perforating devices.				
Nonsterile equipment (e.g. mayo stands, C arms) should be covered with sterile barrier materials. Only sterile items should touch sterile surfaces. Sterile barrier material should be applied to any equipment adjacent to the sterile field.				
All personnel moving in/around sterile field do so in manner to maintain sterility – e.g.. ⇨ Staff do not turn back to sterile field ⇨ Scrubbed personnel pass front to front or back to back ⇨ Separation of sterile team from non-sterile team maintained ⇨ Unscrubbed personnel do not pass between two sterile fields				
Anesthesiology:				
Drainage bags (e.g. foley) kept off the floor				
Aseptic practice used for IV tubing, fluids, medications – injection ports swabbed prior to access				
Sterile equipment including IV solution/tubing is assembled **immediately** prior to use				
Aseptic practice used for all invasive procedures: (epidurals, blocks, IV insertion)				
Anesthesia cart appears clean - degermer readily available				
Re-usable personal equipment (e.g. stethoscope) cleaned between cases				
OSHA/Bloodborne Pathogen Standard:				
Appropriate eye protection used				
Sharps containers not overfull				
Sharps are passed in a basin or by using neutral zone rather than by hand				
Sharps safety devices utilized where available				Devices used:
General Infection Prevention and Control:				
Sterile team removes gloves and washes hands at end of case				
Personnel appear free from communicable disease (no open skin lesions on hands/face/forearms)				
Clean, sterile, and soiled items are kept separate				
Used sterile instruments/equipment ransported to CSP for decontamination and sterilization				

SAMPLE PLAN OF CARE: INFECTION PREVENTION FOR PATIENTS UNDERGOING ORTHOPEDIC SURGERY

Nursing Diagnosis: Risk for Infection

Outcome: The patient will be free from signs and symptoms of postoperative surgical site infection.

Interventions:

- Confirm patient compliance with preoperative skin preparation (as appropriate)
- Implement strict aseptic practices for:
  - Establishing and maintaining the sterile field:
    - Opening supplies and equipment for the procedure
    - Draping the patient and equipment
  - Preparing the patient's skin; removing hair, as necessary
  - Controlling traffic patterns in the OR
  - Ensuring perioperative environmental sanitation
  - Adhering to standard and transmission-based precautions
  - Dressing wound at completion of the procedure
  - Caring for incision sites, invasive-devices sites, urinary drainage systems, and other drainage systems
- Protect from cross-contamination
- Initiate traffic control
- Prepare for pulsatile lavage or irrigation, as needed
- Initiate antibiotic therapy preoperatively and/or intraoperatively per physician's orders; verify medication allergies prior to antibiotic administration
- Establish a normothermia maintenance plan.
- Implement procedure-specific activities, such as using body evacuation suits and pulsatile lavage
- Anticipate equipment needs
- Check equipment function
- Implement safety precautions when using equipment
- Sterilize instruments according to facility policy and procedure and the manufacturer's guidelines:
  - Minimize the use of flash sterilization; use only in selected clinical situations and in a controlled manner
  - Flash sterilization should *not* be used for implantable devices except in cases of emergency when no other option is available
- Handle implants according to the manufacturer's recommendations
- Classify surgical wound according to the CDC
- Monitor for signs and symptoms of infection
- Minimize the length of invasive procedure by planning care
- Maintain continuous surveillance to detect and prevent potential adverse clinical events
- Administer care to wound sites
- Administer care to invasive device sites
- Evaluate factors associated with increased risk for postoperative infection at the completion of the procedure

Infection event analysis

WHAT CAN WE LEARN FROM THIS?

The Patient

Describe patient history.

The Course
Describe clinical course of patient and the hospital-acquired infection detail.

Review: Invasive devices, insertion dates and other contributing factors, (pre-op antibiotics if surgical patient)

Review: Any recalls or devices that may have been associated with infection. Report any association with recalled devices or products

Identify : patient characteristics that may be associated with course
Summarize; Modifiable and non-modifiable patient risk factors

Positive Findings
Summarize documentation or observed compliance with infection prevention measures :

Opportunities for Improvement
Summarize infection prevention measures that could have prevented Infection :

Lessons Learned
Share lessons learned from this patient and how compliance or procedure changes may prevent infection in other patients.

Glossary of Terms

Ambulatory Surgery Center (ASC) : An ASC is a health care facility that specializes in providing surgery, including certain pain management and diagnostic (e.g., colonoscopy) services in an outpatient setting in which the patient does not require an overnight hospital stay.

Fulminanat: Occurring or flaring up suddenly and with great severity. A potentially fatal complication.

Hematogenous: Originating in or spread by the blood.

Implant: A nonhuman-derived object, material, or tissue that is permanently placed in a patient during an operative procedure and is not routinely manipulated for diagnostic or therapeutic purposes. Examples include: porcine or synthetic heart valves, mechanical heart, metal rods, mesh, sternal wires, screws, cements, and other devices

Pathogenesis : The origination and development of disease

Perioperative: The period of time immediately before, during and after surgery.

Phagocytosis: The engulfing and destruction of phagocytes which serves as an important defense mechanism against infection by microorganisms

Phagocyte: A white blood cell that consumes and destroys foreign material (such as microorganisms) and debris

Post discharge surveillance: The process used to seek out infections after patients have been discharged from the hospital. It includes screening a variety of data sources, including re-admissions and emergency department visits.

Toxin: One of a number of poisons produced by certain plants, animals, and bacteria. Frequently used to refer specifically to a particular protein produced by some higher plants, animals and pathogenic (disease-causing) bacteria

Work Around: A workaround is a method, sometimes used temporarily, for achieving a task or goal when the usual or planned method isn't working or is difficult or time consuming to implement.

EXHIBIT 14

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Non-pharmacologic Prevention of Surgical Wound Infection

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Wound infections are serious and relatively common postoperative complications. They are generally detected five to nine days after surgery and are usually attributed, even by surgeons, to poor surgical technique or failure to maintain sterility. However, it has been known for decades that all wounds become contaminated, often by bacteria from the skin or within the patient, and that it is host defense mechanisms that prevent most contamination from developing into clinical infections. Host defense is especially important during the initial hours following contamination, i.e., the immediate perioperative period.

As might thus be expected, factors that improve host defense reduce infection risk. Many of these are under the direct control of anesthesiologists and are at least as important as appropriate use of prophylactic antibiotics, which halve infection risk [1]. This article will review non-pharmacologic methods of reducing infection risk, with special emphasis on methods available to anesthesiologists.

Background

Wound infections are among the most common serious complications of anesthesia and surgery [2–4]. For example, based on the CDC's Study on the Effect of Nosocomial Infection Control (SENIC), the wound infection risk in patients undergoing colon surgery ranges from 9 to 27%, depending on the duration of surgery, degree of contamination of the wound, and number of underlying diseases [5]. On average, the wound infection rate following colon resection lasting > 2 hours is reported to be about 15% in most hospitals [5]. More recent values are somewhat lower, but the risk of infection remains distressingly high.

The morbidity (and related cost) associated with surgical infections is considerable; estimates of prolonged hospitalization vary from 5 to 20 days per infection [2,5,6]. Moreover, after-hospital costs are higher because patients recovering from wound infections are usually discharged before the wound closes entirely, and thus require dressing changes 2 to 3 times daily. The required supplies are costly, and home-nursing visits may be necessary. Despite the substantial reduction in wound infection rates resulting from the universal implementation of sterile technique and prophylactic antibiotics, the incidence of perioperative wound infections remains so high, and so costly, that interventions producing even small further decreases in the infection rate must be considered seriously.

Various factors influence development of wound infections, including 1) character and magnitude of contamination; 2) effects of hemostasis, foreign bodies, damaged tissues, *etc.* on

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the local milieu; 3) wound perfusion, which delivers immune components such as oxygen, inflammatory cells, growth factors, cytokines, and nutritional components including amino acids, glucose, and insulin; 4) antibiotic administration; and 5) immune function [7,8]. Non-specific or "natural" immunity is the most important host defense following acute bacterial contamination, particularly with the most common surgical pathogens, including *S. Aureus*, *Klebsiella*, *E. coli*, *Candida*, and *Enterococcus* [2,3]. Non-specific immune responses include opsonization of bacteria, granulocyte demargination, diapedesis, phagocytosis, and both oxygen-dependent and non-oxidative bacterial killing [9]. Among these, oxidative killing by neutrophils dominates.

The first few hours following bacterial contamination constitute a *decisive period* during which infection is established [10]. The effects of antibiotic administration and of hypoperfusion are especially important during this period. For example, antibiotics limit infection when given within 3 hours of bacterial inoculation but are ineffective when given more than 3 hours after inoculation [7,11]. Similarly, wound hypoperfusion (achieved by epinephrine infiltration or "dehydration shock") aggravates test infections when induced up to 2.5 hours after the inoculation, but has no effect when induced later [10]. Techniques aimed at improving resistance to surgical wound infections are thus most likely to succeed if implemented during the decisive period. It is because the decisive period is so important that interventions restricted to the perioperative period influence wound infection risk, even though infections are usually detected clinically 5–10 days after surgery.

Maintaining Normothermia

Perioperative Thermal Homeostasis

General [12] and neuraxial [13] anesthesia profoundly impairs thermoregulatory control. Consequently, nearly all unwarmed surgical patients become hypothermic. Hypothermia results initially from a rapid core-to-peripheral redistribution of body heat [14,15] and is followed by a linear reduction in core temperature that results from heat loss exceeding heat production. Even mild perioperative hypothermia has been causally linked to numerous severe complications including increased blood loss [16] and transfusion requirement [17], morbid myocardial outcomes [18], prolonged post-anesthetic recovery [19] and hospitalization [6], negative nitrogen balance [20], post-anesthetic shivering [21–23], and thermal discomfort [24]. Hypothermia also increases the risk of surgical wound infection.

Hypothermia Reduces Host Defense

Hypothermia may facilitate perioperative wound infections in two ways. First, sufficient intraoperative hypothermia triggers thermoregulatory vasoconstriction [25,26]. Furthermore, vasoconstriction during recovery is universal in hypothermic patients because brain anesthetic concentration decreases rapidly, allowing re-emergence of thermoregulatory responses [27]. Thermoregulatory vasoconstriction decreases subcutaneous oxygen tension in humans [28], and the risk of wound infection correlates with subcutaneous oxygen tension [29,30].

Second, considerable evidence indicates that mild core hypothermia directly impairs immune function including T-cell-mediated antibody production [31,32] and "non-specific" oxidative bacterial killing by neutrophils [8]. Bacterial killing by neutrophils is apparently reduced as temperature decreases from 41 to 26°C [33,34], although *in vitro* results depend critically on the model used [35]. Decreased killing results at least in part because production of oxygen and nitroso free radicals is oxygen-dependent in the range of oxygen partial pressures found in wounds [36,37].

Patients having initial postoperative temperature near 34.5°C — a typical core temperature in unwarmed patients undergoing major surgery [25,26,38] — require several hours to restore

core normothermia. Bacterial fixation, that is the conversion of contamination into an infection, will thus typically occur while unwarmed patients remain hypothermic. Perioperative hypothermia may thus contribute to surgical wound infections even though the infections usually are not detected until days after surgery. In contrast, it is unlikely that exaggerated bacterial growth aggravates infections in hypothermic patients because the small differences in *in vitro* growth rates within the tested temperature range would *decrease* bacterial growth during hypothermia [39].

Normothermia Reduces Infection Risk

Taken together, these *in vitro* results suggest that hypothermia may directly impair neutrophil function, or impair it indirectly by triggering subcutaneous vasoconstriction and subsequent tissue hypoxia. Consistent with this theory, mild hypothermia reduces resistance to test infections in animals [40,41]. More importantly, 1.9°C core hypothermia (core temperature of 34.7°C) triples the incidence of surgical wound infection following colon resection [6]. These infections were clinically important as indicated by the fact that infected patients, on average, were hospitalized one week longer than the uninfected patients.

A subsequent, uncontrolled, retrospective trial failed to identify a correlation between temperature and infection [42]. This study, though, suffered such serious methodological flaws that it is difficult to interpret [43]. In contrast, a subsequent randomized trial confirmed that both local and systemic warming reduces infection risk — although this may be the only thermoregulatory trial ever published in which core temperature is not reported [44].

Interestingly, hypothermia also increases the duration of hospitalization by 20% even when infected patients are excluded from the analysis — apparently because healing *per se* was significantly impaired (Table 1) [6]. This result is consistent with studies by Carli *et al.* showing that mild hypothermia aggravates postoperative protein wasting [20] and that mild hypothermia reduces collagen deposition (*i.e.*, scar formation) [6].

Excluding brain injury, the major causes of morbidity and mortality in trauma patients are coagulopathy and infection. Since both coagulation [16,17] and resistance to infection [6,44] are profoundly influenced by hypothermia, it is unsurprising that outcome would be improved in normothermic trauma patients [45]. The difficulty with this study, however, is that it is a retrospective analysis. This is a grave limitation because the most seriously injured patients are likely to become most hypothermic. It is thus difficult to be sure that adverse outcomes result from hypothermia *per se* rather than underlying injury. Nonetheless, the result is consistent with known effects of hypothermia.

Supplemental Oxygen

Tissue Oxygenation

Oxidative killing of pathogenic bacteria by neutrophils is the most important immune defense against surgical pathogens [46]. Oxidative killing depends on the production of bactericidal superoxide radicals from molecular oxygen. The rate of this reaction, catalyzed by the NADPH-linked oxygenase, is PO2-dependent. Our studies indicate that neutrophil superoxide production has a Km for oxygen of the NADPH-linked oxygenase of at least 60 mmHg [47]. Consistent with this observation, oxidative killing is oxygen-dependent from 0 to ≥150 mmHg [48].

Inadequate tissue oxygen also impairs tissue repair. Scar formation requires hydroxylation of abundant proline and lysine residues [49]. The prolyl and lysyl hydroxylases that catalyze this reaction depend on the substrate oxygen [49]. The Km for O_2 of prolyl hydroxylase has been variously estimated at 20, 25, and 100 mmHg [50–52]. Even using the most conservative

estimate, proline hydroxylation of collagen will be PO_2-dependent through the range of 0 to at least 200 mmHg, with 90% of the effect occurring by 90 mmHg. Consistent with this estimate, hydroxyproline deposition is proportional to arterial PO2 in rabbits [53] and surgical patients [54].

Oxygen partial pressure in wounds also has a regulatory component [55,56]. For example, it has been known since the 1980's that oxygen regulates angiogenesis [57,58]. Angiogenesis is mediated by micromolar concentrations of H_2O_2 and other reactive oxygen species that activate vascular endothelial growth factor [59,60].

The partial pressure of oxygen in subcutaneous tissues varies widely, even in patients whose arterial hemoglobin is fully saturated. Many factors are known to influence tissue oxygen tension, including systemic and local temperature [28], smoking [61], anemia [62], perioperative fluid management [54], and uncontrolled surgical pain [63]. But as might be expected, one of the most effective (and least expensive) ways of increasing tissue oxygenation is to simply augment inspired oxygen concentration (Fig. 1) [29].

Supplemental Oxygen Reduces Infection Risk

The concept that oxygen is an antibiotic was developed by Knighton and colleagues in a series of *in vitro* and animal studies in the 1980's [64,65]. That tissue oxygenation might have a clinically important effect on wound infection risk was first identified by Hopf et al. [30]. In an observational study, they found that infection risk was inversely proportional to postoperative tissue oxygenation. As a natural consequence of its observational design, this study was confounded by the possibility that tissue oxygenation was worse in sicker patients who had the largest operations — and thus the greatest infection risk — but that there might not be a causal link between the two observations.

The first randomized trial of supplemental oxygen and wound infection risk, Greif et al. [29] involved 500 patients undergoing elective colon resection who were randomly assigned to an inspired oxygen concentration of 30% (n = 246) or 80% (n = 254) intraoperatively and for two hours after surgery. Wounds were evaluated daily by blinded investigators; both pus and a positive culture were required for diagnosis of infection. Wound scores [66] were 5 ± 9 in the patients given 30% oxygen and 3 ± 7 in those given 80%, $P = 0.019$. (All results are expressed as means ± SDs.). There were 13 surgical wound infections in the patients given 80% oxygen and 28 in those given 30% ($P = 0.01$). Supplemental oxygen thus halved infection risk.

In contrast, a subsequent report by Pryor et al. [67] with only 160 patients reported that supplemental oxygen *increases* the risk of infection. It is thus worth considering why the results of Pryor et al. differ so markedly from those of Greif et al. [29]. Pryor et al. [67] did not specify the baseline infection rate they used, making it impossible to confirm their estimate that 300 patients would be required to detect a 40% reduction in the infection rate. But to have an 80% power to detect the 40% risk reduction that they specified from 25% (our baseline) or from 11% (baseline from Greif et al. [29]) would require 540 or 651 patients, respectively; to detect a 40% increase would require 698 or 930 patients, respectively. The study thus appears to have been underpowered and then stopped after only 160 patients were randomized. The authors specify that 160 patients was an *a priori* stopping point, although 53.3% of the anticipated sample size is a curious *a priori* stopping point [68].

A second factor is that Pryor's [67] treatment groups were not homogeneous. For example, in their study patients assigned to 80% oxygen weighed more and were more than twice as likely to have a body-mass index (BMI) exceeding 30 kg/m^2. Patients assigned to 80% oxygen also had longer operations, lost significantly more blood, and required significantly more fluid replacement. Furthermore, Pryor et al. failed to control many variables believed to influence

infection risk including anesthetic, fluid, antibiotic, and pain management. A third limitation of Pryor's study is that wound infections were determined by retrospective chart review; a review that was apparently conducted by unblinded investigators. This insensitive methodology contrasts markedly with the daily wound evaluations by blinded investigators used by Greif et al. It is possible that these methodological problems contributed to a result that is inconsistent with considerable *in vitro*, *in vivo*, and clinical data [69].

The most recent randomized trial of supplemental oxygen, Belda et al. [70] involved 300 patients undergoing colon resection who were randomly assigned to 30% or 80% FiO2 intraoperatively and 6 hours postoperatively. Blinded investigators diagnosed all wound infections using Centers for Disease Control criteria. Baseline patient characteristics, anesthetic management, and potential confounding factors were recorded. Wound infection rates were compared with chi-square analysis. Logistic regression was used to assess the contribution of potential confounding factors. Surgical wound infection occurred in 24.4% of patients receiving 30% oxygen, but only 14.9% of those receiving 80% oxygen (P=0.04). After adjustment the relative risk of infection in patients given supplemental oxygen was 0.46 (P=0.04). Supplemental inspired oxygen thus reduced wound infection risk by roughly a factor of two.

The most recent trial related to supplemental oxygen and wound infection by Myles et al. evaluated substituting supplemental oxygen (80%) for 70% nitrous oxide in 30% oxygen [71]. Infection risk in the patients given supplemental oxygen was significantly reduced, by about 25%. This study differs from previous ones, though, in varying both nitrous oxide and oxygen concentration. It is thus impossible to determine from the results of Myles, et al whether the observed reduction in infection risk resulted from avoidance of nitrous oxide or the beneficial effects of supplemental oxygen.

There are at least three reasons why nitrous oxide might increase infection risk and the authors' hypothesis was that nitrous oxide would reduce host resistance. However, another recent outcome trial, Fleishmann et al. [72], specifically compared infection risk in more than 400 patients who were randomly assigned to 65% nitrous oxide or 65% nitrogen; there was no significant difference between the groups. It thus seems likely that reduced infection risk in the patients of Myles et al. [71] results from supplemental oxygen rather than nitrous oxide toxicity *per se*. This trial thus provides additional support for the antibiotic effect of supplemental oxygen.

There have thus now been three randomized trials specifically evaluating the effect of supplemental oxygen on surgical wound infection. Two trials, with a total of 800 patients, each found that 80% FiO_2 reduced infection risk by a factor of two. In contrast, one small study — with only 160 patients and substantial methodological problems — found just the opposite. Furthermore, an additional study with 2,000 patients that found that substituting supplemental oxygen for nitrous oxide significantly reduces infection risk [71]. Since nitrous oxide, *per se*, does not increase infection risk [72], it is reasonable to consider this study as additional confirmation that supplemental oxygen reduces infection risk. Supplemental oxygen should thus be provided when practical (Table 2).

In each trial, supplemental oxygen was provided intraoperatively; however, postoperative treatments differed. In Greif et al. [29] and Pryor et al. [67] supplemental oxygen was continued for two postoperative hours. In contrast, oxygen was continued for six postoperative hours in Belda et al. [70] and was restricted to the intraoperative period in Myles et al. [71]. There is currently no study that directly compares intraoperative oxygen only with the combination of intraoperative and postoperative oxygen. The extent to which supplemental *postoperative* oxygen contributes to reduced infection risk thus remains unclear.

Supplemental Oxygen is Safe

The major complication associated with brief periods of oxygen administration is pulmonary atelectasis. Concern about atelectasis is appropriate because it occurs in up to 85% of patients undergoing lower abdominal surgery and is thought by some to be an important cause of morbidity [73–75]. Two mechanisms contribute to perioperative atelectasis: compression and absorption. Compression results from cephalad displacement of diaphragm, decreased compliance, and reduced functional residual capacity [76]. To some extent, these factors contribute with any anesthetic technique. Absorption, in contrast, is defined by uptake of oxygen from isolated alveoli and results from administration of high oxygen partial pressures. Administration of 100% oxygen, even for a few minutes, causes significant postoperative atelectasis *via* this mechanism [74,77].

It is important, though, to distinguish between 100% intraoperative oxygen, which does produce atelectasis, and 80% oxygen, which does not [78]. Akça, et al. have shown that 80% perioperative oxygen does not cause atelectasis. Atelectasis was evaluated with computerized tomography the morning after open colon resection. Relatively small amounts of pulmonary atelectasis were observed on the CT scans, and the percentages did not differ significantly in the patients given 30% oxygen (2.5 ± 3.2%) or 80% oxygen (3.0 ± 1.8%, Fig. 2). Pulmonary function was virtually identical in the two groups.

Hyperoxia causes peripheral vasoconstriction, reduced cardiac output, and slight bradycardia [79], a response that is not sympathetically mediated [80]. In contrast, hypoxia — of a magnitude that is probably common in postoperative patients — is associated with cardiac rhythm disturbances [81] that are prevented by supplemental oxygen [82].

Surgery, anesthesia, cardiopulmonary bypass, and mechanical ventilation each independently impair pulmonary immune defenses [83–85]. Hyperoxia, in contrast, provokes pulmonary expression of inflammatory cytokines which in turn helps maintain phagocytosis and oxidative killing by alveolar macrophages (Fig. 3) [86]. It is likely that this response helps patients resist pneumonia, but could well become harmful over long periods of time or in the context of other factors promoting pulmonary inflammation.

Operating room fires can result in substantial injury to the patient and health care providers. In United States, there are approximately 2,260 reported hospital fires per year, resulting in 1 death and 130 injuries. But among these, fewer than 100 occur in operating rooms and of those, only a small fraction result in injury.

As might be expected, oxygen facilitates ignition of flammable material such as operating room draping and speeds propagation of fire once ignited. However, oxygen is normally contained within an anesthesia circuit or well-away from ignition sources such as electrocautery devices. Concerns about operating fire should thus not normally prevent clinicians from providing supplemental oxygen, and especially not in patients at risk for wound infection since infections are much more common than fires. Even open oxygen (such as provided by nasal prongs) dissipates in less than 10 cm and is unlikely to contribute to fire risk unless the ignition source is immediately proximate to the oxygen source [87].

Surgical Site Preparation

It is widely believed that removing hair at the operative site reduces contamination and, therefore, infection risk. It thus remains routine to shave surgical sites. In fact, it is well established that avoiding hair removal or using depilatories rather than shaving reduces infection rates after clean operations [88]. Furthermore, infection rates are reduced when hair is clipped rather than shaved, even when hair is removed on the day of surgery [89]. The reason,

presumably, is that shaving injures skin, thus allowing surface bacteria to penetrate. If hair removal at the incision site is considered necessary, it should thus be performed with clippers during the immediate preoperative period. A corollary is that patients can be warned not to shave their operative sites before surgery, as some shave in an effort to be helpful.

Smoking

Two European studies, published in 1993 and 1996, each showed that smokers have a markedly increased risk of surgical wound infection. These results were considered unsurprising since smoking a single cigarette markedly reduces tissue oxygenation for one hour [61]; tissues are thus nearly constantly hypoxic in "pack-a-day" smokers.

Interestingly, though, three subsequent large trials published in 2000 and later, again from Europe, show no relationship between smoking and infection risk (Table 3) [29,70,72]. The reason, presumably, is that smoking is no longer permitted in hospitals. While smoking obviously produces numerous adverse effects, it no longer appears to be a specific risk factor for development of surgical wound infection.

Glucose Control

Diabetic patients are at increased risk for all kinds of infectious complications and have two-to-three times the risk of surgical wound infection as nondiabetic patients after cardiac operations. In diabetic patients having gastrointestinal or cardiac operations, hyperglycemia (blood glucose exceeding either 200 or 220 mg/dL) is associated with wound infection risk [90,91]. However, it is important to distinguish the long-term peripheral micro-vascular disease of diabetes (which cannot be acutely reversed) with the immediate effects of perioperative hyperglycemia.

There are nonetheless reasons to believe that hyperglycemia *per se* increases infection risk. For example, the risk of SSI for both diabetic and nondiabetic patients is doubled in cardiac surgical patients when blood glucose exceeds 200 mg/dL in the first 48 hours; interestingly, half of the observed hyperglycemic episodes occurred in nondiabetic patients [92].

In an observational trial, Furnary et al. demonstrated a significant reduction in deep sternal wound infections when perioperative insulin management was switched from subcutaneous administration using a sliding scale to a continuous insulin infusion [93]. Rigorous postoperative glucose control using an aggressive insulin infusion protocol has also been shown to reduce multiple organ failure, sepsis, and mortality in critical care patients [94]. This study, though, is the only published prospective evidence that tight perioperative glucose control improves outcome — and focused on cardiac surgical patients admitted to a critical care unit. Whether this finding can be extrapolated to other surgical patients remains to be determined.

It is worth noting, though, that glucose control differs from the other interventions discussed in this article. The others are all simple-to-implement, inexpensive, and pose little or no risk. Tight glucose control, in contrast, requires critical care with all the expense that implies, and includes a distinct risk of hypoglycemia. Further study will be required to determine which patients benefit from tight glucose control and whether outcomes improve sufficiently to justify the difficulty and expense.

Potential, But Unproven Interventions

Vascular Volume

Mild-to-moderate reductions in vascular volume trigger peripheral vasoconstriction to maintain nearly normal blood pressure. However, well-maintained arterial pressure and central

organ perfusion comes at the expense of peripheral perfusion, which can be reduced substantially by even small volume deficits. Blood pressure (and urine output) are thus poor indicators of peripheral perfusion [95].

As might thus be expected, peripheral perfusion and oxygenation were better in surgical patients given 16–18 $mL \cdot kg^{-1} \cdot h^{-1}$ than in those given 8 $mL \cdot kg^{-1} \cdot h^{-1}$. The tissue oxygen tension was greater in the high volume group in both the intraoperative (81 ± 26 mmHg vs. 67 ± 18 mmHg, $P = 0.03$) postoperative periods (77 ± 26 mmHg *vs.* 59 ± 15 mmHg, $P = 0.03$). These results suggested that simply providing supplemental fluid might reduce infection risk. There is also evidence that titrating perioperative hydration to tissue oxygenation results in more fluid administration and better wound healing [96].

Unfortunately, the results of a subsequent clinical outcome study were less encouraging [97]. Patients undergoing open colon resection were randomly assigned to small (8 mL·kg−1·h−1) or large volume (16–18 mL·kg−1·h−1) fluid management. Infection rates were nearly identical and the study was stopped on a futility basis after about 250 patients were enrolled. It is important to recognize, though, that this study was underpowered and a clinically important effect of fluid management on infection risk remains possible. Other studies identify either improved [98,99] or worsened [100] composite complication rates in patients given larger fluid volumes. It is thus unclear from available literature how fluids should be managed to minimize infection risk. Furthermore, the results are likely to vary as a function of type of surgery, type of fluid, or by dosing scheme (*i.e.*, goal-directed *vs*. mL/kg).

Pain Relief

Postoperative pain provokes an autonomic response that markedly increases adrenergic nerve activity and plasma catecholamine concentrations [101]. A consequence is arteriolar vasoconstriction. Reduced peripheral perfusion, in turn, would thus be expected to decrease tissue oxygen partial pressure.

In fact, this theory was confirmed by Akça et al. [63] who showed that tissue oxygen partial pressures were 25 mmHg greater in patients having knee arthroplasty when their pain was aggressively treated (Fig. 4). Whether this translates into lower infection risk has yet to be demonstrated, although a 25-mm increase is probably clinically important [30]. But, of course, patients deserve adequate analgesia even if pain relief proves not to reduce infection risk.

Hypercapnia

The primary determinants of tissue oxygen availability are arterial oxygen content, cardiac output, and local perfusion [102–104]. An important, but often overlooked, influence on cardiac output is arterial carbon dioxide partial pressure [105]. For example, hyperventilation and hypocapnia decrease cardiac output, which in turn decreases blood flow and oxygen tension in brain and splanchnic organs [106–108]. Hypocapnia also shifts the oxyhemoglobin curve leftward and restricts oxygen unloading at the tissue level.

Hypercapnia, in contrast, increases cardiac output, apparently via sympathetic nervous system activation, and also improves oxygen extraction. Consequently, hypercapnia increases oxygen availability to tissue [109]. Since hypercapnia during cardiopulmonary bypass does increase tissue oxygenation (Akça, et al; unpublished data), the increase observed in volunteers and routine surgical patients presumably results largely from an increase in cardiac output, rather than primary vasodilation *per se*.

Hypercapnia also causes a complex interaction between altered cardiac output, hypoxic pulmonary vasoconstriction, and intrapulmonary shunt with the result being a net increase in PaO2 at a given inspired oxygen concentration [110]. But even at a given PaO2, there is a linear

relationship between arterial carbon dioxide tension and cardiac output and subcutaneous oxygenation. In fact, each mmHg increase in arterial carbon dioxide resulted in a 0.8 mmHg increase in subcutaneous oxygenation in volunteers [111]. The increase was even more impressive in surgical patients, with subcutaneous oxygenation increasing from 63 ± 14 at a PaCO2 of 30 mmHg to 89 ± 19 at a PaCO2 of 45 mmHg (Fig. 5) [112]. These data suggest that maintaining slight hypercapnia, a simple and inexpensive maneuver, may reduce infection risk. However, this theory has yet to be confirmed.

Summary

Surgical site infections are among the most common serious perioperative complications. Infections are established during a decisive period lasting a few hours after contamination. Adequacy of host immune defenses is the primary factor determining whether inevitably wound contamination progresses into a clinical infection. As it turns out, many determinants of infection risk are under the direct control of anesthesiologists — factors that are at least as important as prophylactic antibiotics.

Major outcome studies demonstrate that the risk of surgical wound infection is reduced three-fold simply by keeping patients normothermic. Infection risk is reduced by an additional factor of two by providing supplemental oxygen (80% *vs*. 30%) during surgery and for the initial hours after surgery. The contribution, if any, of other factors including tight glucose control, fluid management, and mild hypercapnia have yet to be suitably tested. But it is clear that anesthesiologists can substantially reduce the risk of wound infection simply by providing supplemental oxygen and keeping patients normothermic.

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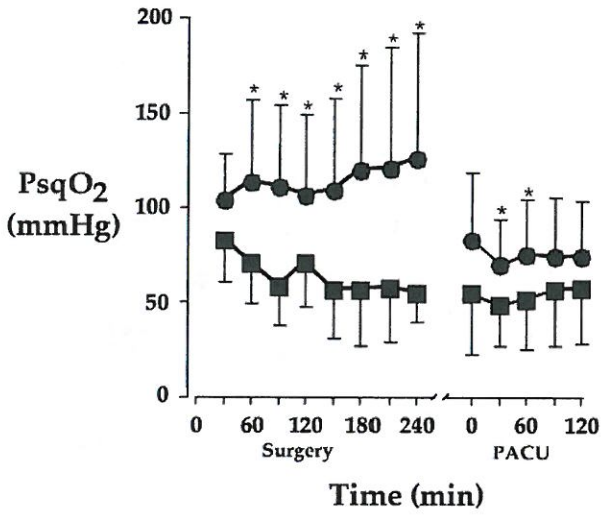

Fig. 1.

Subcutaneous oxygen tension, the primary determinant of wound infection risk, during surgery and in the postoperative care unit (*P < 0.01) [29]. Tissue oxygenation was measured in a surrogate wound on the upper arm. Intraoperative tissue oxygen partial pressure was doubled by supplemental oxygen (FIO_2 = 80% *vs.* 30%); the effect was less during the postoperative period. Results are expressed as means ± SDs.

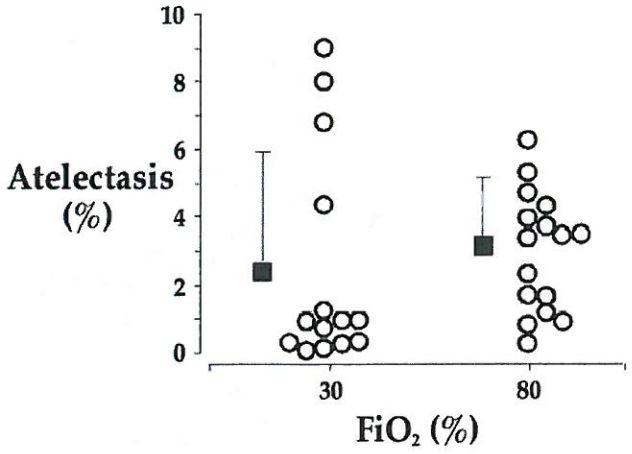

Fig. 2.

From Akça et al. [114] Relatively small amounts of pulmonary atelectasis were observed on the CT scans, and the percentages did not differ significantly in the patients given 30% oxygen (2.5 ± 3.2%) or 80% oxygen (3.0 ± 1.8%). Results are shown for individual patients, along with the group means and SDs. These data provided a 99% chance of detecting a 2% difference in atelectasis volume at an alpha level of 0.05. Poorly-aerated regions were also comparable between the groups (9.5 ± 4.4% in the patients given 30% oxygen *vs*. 10.3 ± 4.2% in the patients given 80% oxygen).

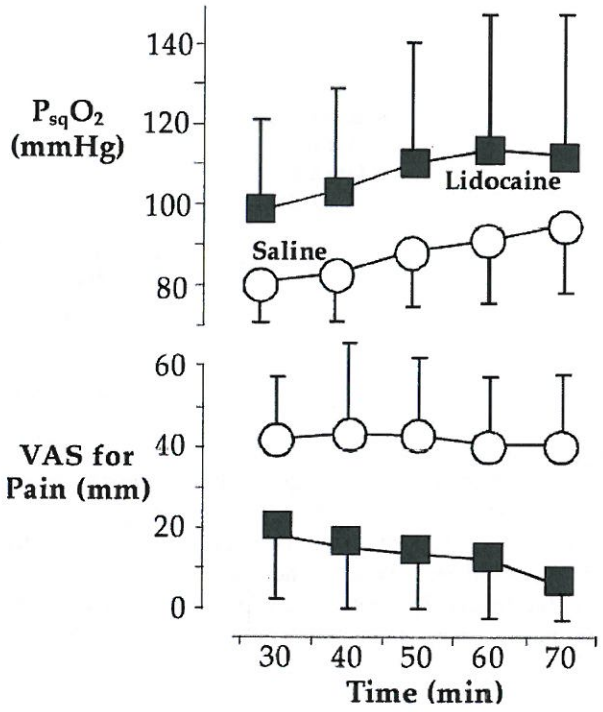

Fig. 3.

From Kotani et al. [86] the fraction of alveolar macrophages ingesting opsonized and non-opsonized particles during anesthesia with 100% (n = 30, circles) and 30% (n = 30, squares) inspired oxygen. Asterisks (*) indicate statistically significant differences ($P < 0.05$) from elapsed time zero in each group; pounds signs (#) identify significant differences ($P < 0.01$) between the two groups. Data are expressed as means ± SDs.

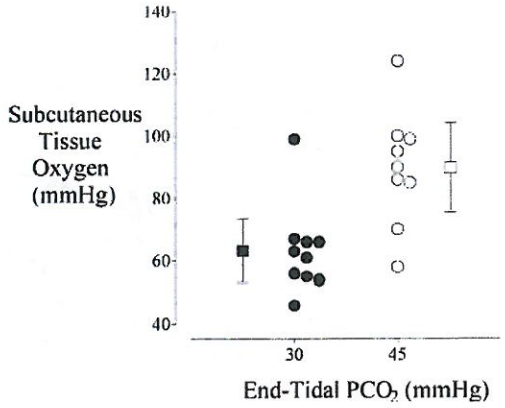

Fig. 4.

A of pain scores and tissue oxygenation in patients given intra-articular lidocaine (squares) or saline (circles). Pain scores, on a 100-mm visual-analog scale, were much larger in patients given saline, and their tissue oxygen partial pressures averaged 25 mmHg less. All values differed significantly between the two groups; data are presented as means ± SDs. Reprinted from *The Lancet*, 354, Akça O, Melischek M, Scheck T, et al. Postoperative pain and subcutaneous oxygen tension. Page 41, Copyright (1999), with permission from Elsevier [63].

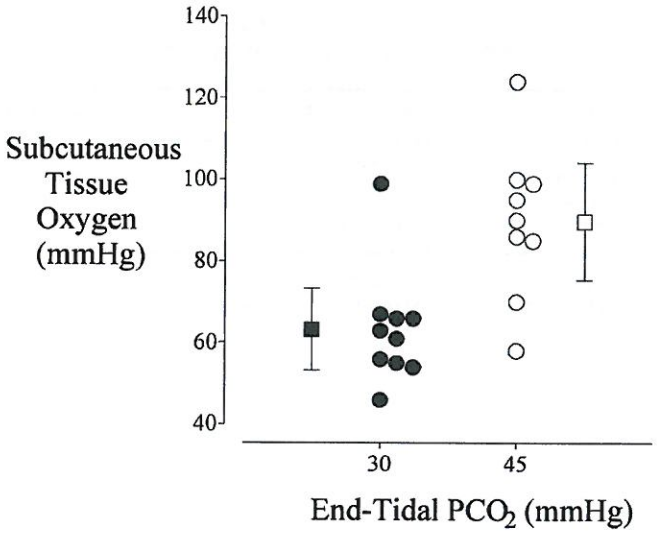

Fig. 5.

From Akça et al. [112] a study subcutaneous tissue oxygen as a function of end-tidal PCO_2 in patients undergoing major surgery. Measurements were made on the lateral aspect of the upper arm with a polargraphic electrode system. The mean oxygen tension in the group given 45 mmHg $C0_2$ was significantly greater ($P = 0.014$) than the group given 30 mmHg. Results are presented as means ± SDs.

Table 1

Maintaining Perioperative Normothermia Reduces Wound Infection Risk and Shortens Hospitalization.

	Normothermic	Hypothermic	*P*
Number	104	96	
Temperature (°C)	36.6 ± 0.5	34.7 ± 0.6	<0.001
Infection (%)	6	19	<0.01
Hospitalization (days)	12.1 ± 4.4	14.7 ± 6.5	0.001

A randomized, blinded trial from Kurz et al. [6]. Maintaining normothermia reduced infection risk by a factor of three and reduced the duration of hospitalization by 20%. The reduction in hospitalization persisted even when analysis was restricted to uninfected patients.

Table 2

Randomized Trials Evaluating the Effect of Supplemental Oxygen on Wound Infection Risk.

	Number	FIO_2=30% (%infected)	FIO_2= 80% (% infected)	*P*
Greif et al. [29]	500	11	5	0.01
Pryor et al. [67]	160	11	25	0.02
Belda et al. [70]	300	24	15	0.04
Myles et al. [71]	2000	10	7.7	0.03

With the exception of a small study by Pryor, et al, available randomized trials show that supplemental oxygen significantly reduces infection risk.

Table 3

Smoking and Wound Infection Risk.

	Year	Non-Smokers (% infected / n)	Smokers (%infected / n)	*P*
Kurz et al. [6]	1996	7% / 148	22% / 76	<0.001
Greif et al. [29]	2000	8% / 283	8% / 122	NS
Fleishmann et al. [72]	2005	16% / 335	17% / 81	NS
Belda et al. [70]	2005	22% / 187	30% / 46	NS

A study published in 1996 observed that infection risk was tripled in smokers. In an additional study from 1993, bacterial infection risk was doubled from 15 ± 3% to 33 ± 8%, but these values include pneumonia as well as surgical wound infections [113]. In contrast, three subsequent studies observed no relationship between smoking and infection risk. The probable explanation is that after 2000, smoking was no longer allowed in hospitals. Smoking thus no longer appears to be an important risk factor for development of surgical wound infection.

EXHIBIT 15

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

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In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

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DEPOSITION OF ALBERT P. VAN DUREN

VOLUME I, PAGES 1 - 326

MARCH 7, 2017

(The following is the deposition of ALBERT P. VAN DUREN, taken pursuant to Notice of Taking Deposition pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, via videotape, at the offices of Ciresi Conlin L.L.P., 225 South 6th Street, Suite 4600, Minneapolis, Minnesota, commencing at approximately 9:00 o'clock a.m., March 7, 2017.)

while the forced-air warming unit is being operated.
Q. It's there to check the protective effect of the laminar flow system.
A. That -- that's right.
Q. Correct?
A. But the -- but the particulates are generated externally from the warming unit. They're not being ejected from the warming unit, they're being in -- introduced --
Q. I -- I never said they're being ejected from the warming unit.
MR. BLACKWELL: You may finish your answer.
A. But I'm -- but I'm explaining the difference between --
Q. Okay.
A. -- a -- a study where you're looking at particulates that emanate from the warming unit as opposed to a study where the particulates were placed within the room to check the protective effect of the laminar airflow.
Q. Well I agree with you that the study that is the standard that's used for the -- for the Sessler article, which is a DIN standard, is not -- is not used to count particles. Correct?
A. I'm not sure what you mean by that exactly.

Q. It's -- it's to determine whether or not --
The standard that was used in that study is to determine whether or not the operating room theater complies with a DIN standard; correct?
A. Well it --
The laminar airflow system within the operating room, yes.
Q. Whether it -- and -- strike that.
And to comply with the DIN standard in that Sessler article, you just have to have a protective effect of two; correct?
THE REPORTER: I'm sorry --
MR. BLACKWELL: I object to the form of the question.
Q. To have --
To comply with the DIN standard, D-I-N, you have to have a protective effect of two.
A. Yes.
Q. Okay. That standard was not created to compare different modes of patient warming.
A. Well in fact there are no standards for that.
Q. Okay. But that was the purpose of the study that you, 3M, funded, was to compare the particle count above the surgical site between forced-air

warming and conductive warming.
A. Forced-air warming and no warming I believe.
Q. And no warming, correct. I'm sorry.
Correct?
A. Yes.
Q. Okay. But the DIN standard was not created to perform that type of test; correct?
A. Well that's not its main purpose, no.
Q. It's not even its secondary, tertiary, whatever purpose. There's nothing in the DIN standard that -- that exists that says you could also use the standard to calculate particle counts when forced-air warming is used.
A. That's correct.
Q. Okay. Now with the Moretti study, which was --
Are you familiar with the Moretti study that you cited that was --
A. I am.
Q. Do you know what Bair Hugger unit was used in that study?
A. I believe it was a 505E.
Q. And the 505E has less flow than the 505; correct?
A. Yes.

Q. Because the Europeans complained about noise too much. One of the reasons.
A. No.
Q. That's not one --
What's the reason then?
A. The reason is that the motor that's used in the 505 is an induction motor and its speed is proportional to the line frequency, and in Europe, or at least in Italy, the line frequency is 50 hertz as opposed to 60 hertz in the United States.
Q. And was 3M or Arizant or the company involved in any way with the Moretti study?
A. No. Only after I did contact Dr. Moretti to ask him some questions, but this is after the study was published.
Q. And that wasn't done in a laminar flow; correct? That was --
A. That was done in a conventionally ventilated operating room.
Q. Well when you say conventional, is it unidirectional?
A. Well I -- I mean conventional --
Q. Or don't you know?
A. Well conventionally ventilated, that's all I know.

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Hugger is on, the average -- the average particles are higher when the Bair Hugger is off; correct?
MR. BLACKWELL: Same objection, beyond the scope of the 30(b)(6) designation.
A. I would agree that the averages are that way, yes.
Q. And you agree that every single -- every time the Bair Hugger is on, the protective effect is lower than when the Bair Hugger is off.
MR. BLACKWELL: Same objections.
A. Except when it's exactly the same.
Q. When the Bair Hugger is on compared to off.
A. Yes.
Q. Where do you see it being exactly the same?
A. When it's on ambient temperature in Utrecht with the 635.
Q. Oh, you are correct. When the Bair Hugger is on warm as compared to it's off.
MR. BLACKWELL: Same objection.
A. In the warm condition, yes.
Q. Okay. And therefore, you would agree with me that, based on the study that 3M paid for, that the Bair Hugger has an effect, when the Bair Hugger is on warm, has an effect on the protective effect.
MR. BLACKWELL: I object that -- to the form

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of the question and move to strike the comment about the study being paid for.
A. I'm sorry, would you repeat the question?
Q. You agree with me that 3M paid for the study; correct?
MR. BLACKWELL: I object and move -- Object to the form of the question.
MR. ASSAAD: Basis?
MR. BLACKWELL: "Paid for." 3M didn't pay for the study, they funded a study.
MR. ASSAAD: Okay.
Q. 3M funded the study; correct?
MR. BLACKWELL: They didn't go out and buy a study.
Q. 3M funded the study; correct?
A. Yes.
Q. And 3M --
A. Well they funded the -- the company, LUWA, to conduct the study, yes.
Q. They paid LUWA.
A. Yeah.
Q. Okay. And not only that, they paid for your airline ticket and your hotel to go over to Amsterdam; correct? Or to Holland.
A. Yes.

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Q. And they paid for Gary Hansen's air fare and hotel.
A. Yes.
Q. And they paid for your spending money to eat; correct?
A. Yes.
Q. Okay. And therefore, you agree with me that the 3M-funded study here in Sessler indicates that when the Bair Hugger is on warm as compared to the Bair Hugger off, it has an effect on the -- on the particle counts of the sterile field.
A. I would agree that the -- the particles are higher -- the particle counts are higher when the unit is on --
Q. Warm.
A. -- under those conditions, yeah.
Q. Okay. And you agree with me that both Legg and McGovern also indicate higher particle counts or bubble counts when the Bair Hugger is on warm as compared to the Bair Hugger is off.
MR. BLACKWELL: Object to the form of the question.
A. Yes.
Q. So based on all those studies, you agree with me that the Bair Hugger, when it's blowing warm

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air, has an effect on the particle counts in the sterile field.
MR. BLACKWELL: Same objection.
A. It --
I mean it's possible that -- that that's one conclusion you could draw from this data.
Q. Well every single study indicates that, so what is your basis that it's possible and not probable?
MR. BLACKWELL: Object and move to strike counsel's comment/statement. Object to the form of the question.
A. Again, the -- the study at Amersfoort is a different type of study than that conducted by Legg. The -- the study at -- in Amersfoort looked at externally-generated particles in the sterile field; Legg looked at, ostensibly, particles being generated by the forced-air warming unit itself, so it's a different --
These are different kinds of studies.
Q. Legg and McGovern used bubble counts and -- and particle counters.
A. Oh, sorry. Yeah. Okay.
Q. I mean we're --
It doesn't matter where the particles are

coming from. Okay? Because particles are all over the operating room and underneath the operating room table and everywhere. Do you agree?
A. Yes.
Q. Okay. Based on the data that we have today, including the study funded by 3M as well as other studies, every single study indicates that the Bair Hugger increases the particle count over the sterile field; correct?
A. In absolute numbers, yes.
Q. Yes. Okay. And you have no internal studies to refute that; correct?
A. No, we don't.
Q. What's defendants' knowledge and analysis of third-party testing regarding whether or not the Bair Hugger causes surgical-site infection?
A. Well again, the analysis that I showed you that was done with the CDC data, for example. And the secular trend of deep joint infection over the last decade or so has generally declined in hip and knee implant surgery, so at a -- at a macro level there doesn't appear to be an increase in the number of these infections despite the fact that patients are generally older and sicker and there are more of them now than there were a decade ago.

Q. I don't see a decrease in Exhibit 77 of infection rates. Do you?
A. Well they haven't --
So in this particular exhibit the -- the rates haven't changed dramatically from, say, 1998 or 1997 to 19 -- or to 2012, but if you look at the -- if you look at the second one that I have done using the data from Parvizi, there clearly is a trend in -- of decreased surgical-site infections, and it's more in line with the kinds of infection rates that we see at individual institutions in the United States.
Q. Are we talking about the 2001-to-2009 data?
A. The latest paper, whichever -- whichever data set that is.
Q. Okay. Well his own paper showed an increase over the -- from 2001 to 2009. Even though it was a slight increase, it was an increase.
A. No, I don't think that's correct. The data that I have shows a -- a clear decline in infection -- in joint infection rates over that time period.
Q. I want to print up that article for you. We'll move on and I'll get it printed up and we can talk about it.
We're talking about the 2012 article; correct?

A. I believe that's the corr -- yeah, I believe that's the correct one.
Q. Any other articles or studies that you rely upon with respect to third-party testing regarding surgical-site infection?
A. Well the Kimberger article would -- for example, although that's not surgical-site infection, but --
Q. I guess a preface -- I don't mean to interrupt -- I want to talk about total hip and total knee arthroplasty.
A. Yes.
Q. Okay.
A. Right.
Q. Isn't it true that there's a pilot study being performed right now funded by 3M in the U.K.?
A. Yes.
Q. Okay. Is that study started?
A. I don't think it started recruiting yet.
Q. Okay. And that's going to look at surgical-site infections for a certain type of orthopedic surgery; correct?
A. Yes, as one of the outcomes.
Q. And one of the investigators is Mike Reed; correct?

A. Yes.
Q. Okay. And 3M, in its analysis of studies, has actually criticized Mike Reed; correct?
A. Yes.
MR. BLACKWELL: I think this is a place for a break.
MR. ASSAAD: Sure.
THE REPORTER: Off the record, please.
(Recess taken.)
BY MR. ASSAAD:
Q. With respect to surgical-site infections and 3M's knowledge and analysis, you would agree with me that there's no reliable study out there that indicates that normothermia reduces the incidence of periprosthetic joint infections; correct?
MR. BLACKWELL: Object to the form of the question.
A. In that particular surgery, I don't believe there are any randomized controlled trials that looked at that question.
Q. There's no studies that looked at that question; correct?
MR. BLACKWELL: Same objection.
A. There may be some retrospective studies, but I -- I don't recall any right now.